87-17

No.

In the Supreme Court

OF THE

United States

OCTOBER TERM, 1986

STEPHEN COWAN, CHESTER DUPONT, LORNA PURKEY, and FREDERICK S. MAYER,
Petitioners,

VS.

BEVERLEE A. MYERS, Acting Director, Department of Health Services, State of California; KENNETH KIZER, Director, Department of Health Services, State of California; DEPARTMENT OF HEALTH SERVICES, State of California; GRAY DAVIS, Controller, State of California; and JESSE UNRUH, Treasurer, State of California,
Respondents.

On Writ of Certiorari to the Court of Appeal, State of California, Third Appellate District

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Does State approval of medical necessity for prior authorization and for post-service payment, (as required by Secs. 14133 and 14133.3 California Welfare & Institutions Code),—both upon its face, and as implemented in fact by the California Medicaid agency, violate the Medicaid Act, (42 U.S.C. Secs. 1396 et seq.) requirement that the treating physician, not the State, make the determination of what treatment and drugs are medically necessary for Medicaid patients?

2. Does the California Medicaid system of prior authorization for medical services and drugs, and post-service review of medical necessity, frequently cause covered services to be unavailable so as to be burdensome, onerous, unreasonable and not in the best interests of California Medicaid recipients, in violation of 42 U.S.C. Sec. 1396a(a)(17), (19) and (22), and, 42 Code of Federal Regulations, Sec. 440.230(b), (c)?

3. Does California's limitation of Medicaid coverage, in Secs. 14133.3 and 14059.5 California Welfare & Institutions Code, to only those services:

> "... reasonable and necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain(,)"

violate the Medicaid Act, 42 U.S.C. Secs. 1396, 1396a(a)(17), (19) and (22), and, 42 Code of Federal Regulations, Sec. 440.230(b)?

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OPINIONS BELOW

The opinion of the Court of Appeal, State of California, Third Appellate District, 187 Cal.App.3d 968, is in Appendix A, p A-1. The unreported opinion of the trial court, (Superior Court, State of California, County of Sacramento), is in Appendix E, p A-49.

JURISDICTION

The judgment or decree to be reviewed is the December 9, 1986 decision of the Court of Appeal, State of California, Third Appellate District, 187 Cal.App.3d 968, (Appendix A, p A-1).

Petition for rehearing was denied January 7, 1987. (Appendix B, p A-39). The duly filed Petition for Review, (Appendix F, p A-66), was denied April 2, 1987 by the California Supreme Court, 4-to-3. (Appendix C, p A-40), without opinion.

The U.S. Supreme Court has jurisdiction for writ of certiorari under 28 U.S.C. Sec. 1257, subsection 3, in that the validity of California statutes, (namely, Secs. 14133, 14133.3 and 14059.5 California Welfare & Institutions Code,[1] are drawn in question as being repugnant to the Medicaid Act, 42 U.S.C. Sec. 1396, 1396a(a)(17), (19), (22), and 42 Code of Federal Regulations, ("C.F.R."), Sec. 440.230(b), (c); and, also, rights of Medicaid recipients-petitioners are specially set up and claimed under the above United States statutes and regulations.

STATUTES AND REGULATIONS INVOLVED

California Welfare and Institutions Code:

Section 14133.3.

(a) The director shall require fully documented medical justification from providers that the requested services are medically necessary to prevent significant illness, to alleviate severe pain, to protect life, or to prevent significant disability, on all requests for prior authorization.

(b) For services not subject to prior authorization controls, the director shall additionally determine utilization controls which shall be applied to assure that the health care services provided and the conditions treated, are medically necessary to prevent significant illness, alleviate severe pain, to protect life, or prevent significant disability. These utilization controls shall take into account those diseases, illnesses, or injuries which require preventive health services or treatment to prevent serious deterioration of health.

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[1] Hereinafter all references are to the California Welfare & Institutions Code, unless otherwise noted.

(c) Nothing in this section shall preclude payment for family planning services or early and periodic screening, diagnosis and treatment services mandated by federal law.

(d) Provisions of this section shall not be applied to mental health services as defined under Division 5 (commencing with Section 5000) or Section 14021, or any other mental health services funded by the Medi-Cal program.

Sec. 14133.

Utilization controls that may be applied to the services set forth in Section 14132 which are subject to utilization controls shall be limited to:

(a) Prior authorization, which is approval by a department consultant, or a specified service in advance of the rendering of that service based upon a determination of medical necessity. Prior authorization includes authorization for multiple services which are requested and granted on the basis of an extended treatment plan where there is a need for continuity in the treatment of a chronic or extended condition.

(b) Postservice prepayment audit, which is review for medical necessity and program coverage after service was rendered but before payment is made. Payment may be withheld or reduced if the service rendered was not a covered benefit, deemed medically unnecessary or inappropriate. Nothing in this subdivision shall supersede the claims processing deadlines provided by Section 14014.3.

(c) Postservice postpayment audit, which is review for medical necessity and program coverage after service was rendered and the claim paid. The department may take appropriate steps to recover payments made if subsequent investigation uncovers evidence that the claim should not have been paid.

Sec. 14059.5.

A service is "medically necessary" or a "medical necessity" when it is reasonable and necessary to protect life, to prevent

significant illness or significant disability, or to alleviate severe pain.

42 U.S.C. Sec. 1396. Appropriations.

For the purpose of enabling each State, as far as practicable under the conditions in such State, to furnish (1) medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services, and (2) rehabilitation and other services to help such families and individuals attain or retain capability for independence or self-care, there is hereby authorized to be appropriated for each fiscal year a sum sufficient to carry out the purposes of this subchapter. The sums made available under this section shall be used for making payments to States which have submitted, and had approved by the Secretary, State plans for medical assistance.

42 U.S.C., Sec. 1396a. State plans for medical assistance.

(a) *Contents*

A State plan for medical assistance must—

(17) *include reasonable standards* (which will be comparable for all groups and may, in accordance with standards prescribed by the Secretary, differ with respect to income levels, but only in the case of applicants or recipients of assistance under the plan who are not receiving aid or assistance under any plan of the State approved under subchapter I, X, XIV, or XVI, or part A of subchapter IV of this chapter, and with respect to whom supplemental security income benefits are not being paid under subchapter XVI of this chapter, based on the variations between shelter costs in urban areas and in rural areas) *for determining eligibility for and the extent of medical assistance under the plan which (A) are consistent with the objectives of this subchapter*[2], . . . ;

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[2] Emphasis supplied.

(19) provide such safequards as may be necessary to assure that eligibility for care and services under the plan will be determined, and such care and services will be provided, in a manner consistent with simplicity of administration and the best interests of the recipients;

(22) include descriptions of . . . (D) other standards and methods that the State will use to assure that medical or remedial care and services provided to recipients of medical assistance are of high quality.

42 C.F.R., Sec. 440.230(b), (c), (d).

(b) Each service must be sufficient in amount, duration, and scope to reasonably achieve its purpose.

(c) The Medicaid agency may not arbitrarily deny or reduce the amount, duration, or scope of a required service under Secs. 440.210 and 440.220 to an otherwise eligible recipient solely because of the diagnosis, type of illness, or condition.

(d) The agency may place appropriate limits on a service based on such critieria as medical necessity or on utilization control procedures.

STATEMENT OF THE CASE

Prior to 1982, the respondent Department of Health Services, ("DHS"), paid for all medically necessary treatment and drugs in respect to services provided by the California Medicaid Act program, (funded one-half by the federal government under the Medicaid Act, 42 U.S.C. Secs. 1396 et seq.).

(This Medicaid Act program is colloquially called "Medi-Cal" by California Medicaid recipients and providers. "Medi-Cal", whenever used herein, refers to and means the Medicaid Act program in California, under 42 U.S.C. Secs. 1396 et seq.) In 1975, the Legislature authorized the Medi-Cal agency to "second-guess" the treating physician by requiring prior authorization by DHS for certain treatment and drugs "based upon a determination of medical necessity," and by authorizing DHS to deny,

payment if "the service rendered was not a covered benefit, deemed medically unnecessary or inappropriate." (Sec. 14133).

In 1982, Sec. 14133.3 was enacted, which reduced Medi-Cal coverage to only that treatement and drugs which:

> " . . . are medically necessary to protect life or prevent significant disability."

Also in 1982, the DHS drastically increased the medical services and medical devices which were subject to prior authorization and post-service review for medical necessity and appropriateness. Also, the Medi-Cal agency in 1982 deleted a half-dozen categories of drugs from the Medi-Cal Drug Formulary. (The Drug Formulary is a list of drugs which may be prescribed without prior authorization.)

In late 1982, petitioners Stephen Cowan, Chester Dupont, Lorna Purkey, and Frederick S. Mayer, filed suit in the Superior Court, State of California, in and for the County of Sacramento, ("Superior Court"), against respondents, (namely, DHS, its director, and the state Treasurer and Controller).[3] The amended complaint alleged, the case was tried upon, and the May 31, 1983, Statement of Decision of the Hon. William A. White, Judge, (Appendix E, p A-49), found that the Medicaid Act was violated in the same respects as set forth in the Questions Presented for Review herein.[4] The Superior Court entered judgment of declaration of rights on May 31, 1983, incorporating the Statement of Decision as part of the judgment. (Appendix D, p A-41). The

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[3] Petitioners Cowan, Dupont and Purkey sued as California Medicaid recipients. Petitioner Mayer is a California resident-taxpayer and pharmacist. Petitioner Cowan died after the trial court judgment. Lorna Purkey is no longer a Medicaid recipient.

[4] The only exception is that, when the case was tried, Secs. 14133 and 14133.3 W&I Code limited Medi-Cal coverage to services "medically necessary to protect life or prevent significant disability." These statutes were amended in 1985 and Sec. 14059.5 W&I Code was added, to broaden Medi-Cal coverage to services medically necessary to protect life, to *prevent significant illness* or significant disability, or to *alleviate severe pain*. (Emphasis supplied).

judgment adjudicated that Sec. 14133.3,—upon its face and as implemented by DHS,—violated the Medicaid Act and regulations because it did not furnish and pay for all medically necessary treatment in Required Services and those Optional Services provided by Medi-Cal, (Clerk's Transcript, ("CT"), 460-470), and, also, to boot, that Sec. 14133.3,—upon its face and as implemented by DHS,—resulted in non-treatment of disease at the entry stage which progresses into serious disease, (CT 462; Reporter's Transcript, ("RT"), 216); and,

—That the Sec. 14133.3 limitation,—upon its face and as implemented by DHS,—violated 42 C.F.R. 440.230(b) because a standard of treatment with the Sec. 14133.3 limitation is insufficient in amount, duration and scope to reasonably achieve its purpose. (CT 460, 467; Findings 11, 14-22, CT 462-467;

—That the Sec. 14133.3 limitation,—upon its face and as implemented by DHS,—violated 42 C.F.R. 440.230(c) because it arbitrarily denied and reduced the amount, duration and scope of Required Services solely because of the diagnosis, type of illness, and condition of the recipients;

—That the prior authorization system, (Sec. 14133),—both upon its face and as implemented by DHS,—violates the Medicaid Act requirement that the treating physician, not the State, make the determination of what treatment and drugs is medically necessary. (CT 467-470, CT 470-474);

—That the prior authorization system, (Sec. 14133),—both upon its face and as implemented by DHS,—frequently causes *covered services* to be unavailable and "is burdensome, onerous, unreasonable and not in the best interests of Medi-Cal recipients," (CT 470-474), and therein (i) violates 42 C.F.R. 440.230(b) because the delivery is insufficient in amount, duration and scope to achieve its purpose; (ii) violates 42 U.S.C. Sec. 1396a(a)(19) which requires the State to "assure" that the services covered will "be provided in a manner consistent with simplicity of administration and the best interests of the recipients."; (iii) violates 42 U.S.C. Sec. 1396a(a)(22) which requires "standards and methods" which "assure that medical or remedial care and services provided to recipients of medical assistance are

of high quality."; and, (iv) violates the Rule of *Beal v. Doe*, 432 U.S. 438, 444, 53 L.Ed.2d 464, 97 S.Ct. 2364, 2371, i.e., that the State plan standards be "reasonable" and "consistent with the objectives" of the Medicaid Act.

Thereupon, in the same Judgment, the Superior Court ordered peremptory writ of mandamus, enjoining respondents from enforcing or implementing Sec. 14133's prevent-death-or-significant-disability limitation, and from enforcing the prior authorization requirements of subsection (a) of Sec. 14133. (Appendix D, p A-42-A-45).

Respondents appealed. Petitioners cross-appealed in respect to the failure of the Superior Court to also enjoin the post-service review of "medical necessity" under subsections (b) and (c) of Sec. 14133.

The Court of Appeal immediately stayed the judgment and writ of mandamus. On December 9, 1986, the Court of Appeal rendered its decision, 2-to-1, (Appendix A, p A-1), entirely reversing the judgment and writ of mandamus. As the Court of Appeal decision shows, the appeal was briefed, argued and decided upon the Questions Presented for Review. Petitioners duly filed their Petition for Review in the California Supreme Court, (Appendix F, p A-66), setting forth therein, once again, the Questions Presented for Review herein. (Appendix F, pp A-66-A-69). Petition for Review was denied April 2, 1987, by the California Supreme Court, without opinion, 4-to-3, (Appendix C, p A-40).

The essence of the trial court findings,—none of which were found by the Court of Appeal to be contrary to or unsupported by the trial evidence,—are set forth as follows:

Trial court Findings 27-31, CT 470-474, (Appendix E, pp A-57 through A-60):

> "27. The Department of Health Services, (Department), has 12 field offices for processing medical TARS,[5]

[5] For prior authorization, providers submit a Treatment Authorization Request,—whence comes the acronym, "TARS".

(RT 345). Only two of these field offices process drug TARS, RT 348, 120), (except for a small drug TAR office serving the three-county Redwood Empire, RT 119, 120). H. Thomas Heerhartz, Chief of the Field Services Branch of Medi-Cal, and responsible for operation of these TAR offices, filed a declaration, (Trial Exhibit 26, paragraph 10), and testified, (RT 360),—and the Court finds,—that:

'Because of fiscal shortages, we are forced to operate with less than the full complement of staff reasonably required to process TARS.'

Medi-Cal consultants who are physicians, make the decisions in respect to non-drug TARS. (RT 297; Heerhartz Declaration, Trial Exhibit 26, paragraph 3). Medi-Cal consultants *who are pharmacists,* make the decisions in respect to drug TARS. (RT 297; Heerhartz Declaration, Trial Exhibit 26, paragraph 3).

. . . The TAR denial goes to the provider. The provider can appeal to the field office administrator,—but the administrator is not a physician or a pharmacist. Telephone TARS are received by a staff of transcribers who take the information, obtain the file, and refer it to the medical or drug consultant, as the case may be. Dr. Lackner testified, and the Court finds, that the transcribers are not all familiar with medical terminology.[6] TAR offices are closed weekends, holidays, and evenings. Although a mailed TAR "turn-

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[6] Dr. Jerome Lackner, formerly, Director of DHS in the 1970's, testified, (RT 229-230), that typically the provider on a telephone TAR is first met with a busy signal; "if you are lucky enough to get the phone to answer," you first get put on hold; "the third obstacle course" is when you get off hold, you speak to the lay transcriber; then you are put on hold again while the transcriber communicates with the Consultant; "sometimes twenty or thirty minutes later, I come again off of hold, and the same person is back on the phone." Now, the lay transcriber asks one more question on behalf of the Consultant, and puts you on hold again "for another ten to twenty minutes. In the meantime, my waiting room is filling up with sick people, my receptionist is getting upset at me . . . ". (RT 229-230; 225-227; 242).

around" time is 1 to 3 days for drug TARS, and 5 to 7.9 days for other TARS, course-of-mail time, and intervening weekends, often add 4 to 5 days to the mailed TAR process. There is no directive or writing from the Director, defining "significant disability", and the lack of definition renders TAR decisions subject to the subjective views of the particular consultant in the TAR decision.[7]

28. All Required Services and all Optional Services are subject to "utilization control" of review for "medical necessity", by prior authorization, (§ 14133(a)), and in billing § 14133(b), (c), 22 Cal.Adm.Code § 51052(d)). The Director has put hundreds of specific medical procedures under prior authorization review for "medical necessity". (Trial Exhibits 3, 4, 5, 6, 9, 10, 11). Many are treated by the Department as "Procedures Generally Excluded From Coverage", (Trial Exhibit 6, 10), although Dr. Lackner testified, and the Court finds, that most of them are generally accepted procedures which are medically necessary when the relevant symptoms appear.

29. In addition to the testimony of Dr. Lackner and pharmacist Mayer, (pp 7-8 herein) on the subject of insufficiency of the Medi-Cal Drug Formulary, the testimony of pharmacists and physicians at the November 19, 1982 Department hearing, established that a substantial range of FDA-approved, generally accepted and medically necessary drugs are not on the Medi-Cal Drug Formulary. These FDA-approved, generally accepted and medically necessary drugs which are not on the Formulary are, to a substantial degree, unobtainable under the TAR process, (Paragraphs 14-21, 27-28, 30 herein.)

30. Dr. Lackner testified, and the Court finds, that: the TAR process in and of itself exerts a burden on providers to the degree that the extra increment in paperwork and time and expense dissuades many of them from treating Medi-Cal

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[7] There is not a single written directive which defines "medical necessity." (RT 338, Joan Vaughan, San Francisco TAR administrator).

patients, (RT 215); that the withholding of medically necessary drugs at the threshold of minor illnesses inevitably leads in many cases to more serious and more expensive illness, (RT 216); that since the § 14133.3 regulations came in, that the denials are more frequent, (RT 230), that the provider time to obtain telephoned TAR approvals has increased, (RT 230); and, the Department on many occasions denies payment for treatment of Medi-Cal patients during times when the TAR office was closed or the TAR could not be obtained in sufficient time, (RT 233-235).[8]

The Court finds that the TAR system, inherently, and as it presently exists, takes control of treatment of the patient away from the physician, (RT 228-231); and that it is professionally impossible for any consultant to obtain enough or proper evidence through the existing TAR system by which to make a professional judgment as to medical necessity. (RT 329).

31. The Court finds that the TAR system inherently, and as it exists, and under § 14133(a), frequently causes Required and Optional Services which are medically necesary to be unavailable to Medi-Cal recipients, and that the procedure is burdensome, onerous, unreasonable and not in the best interests of Medi-Cal recipients." (*Statement of Decision,* CT 470-474).

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[8] The Medi-Cal system of retroactive denial of services provided when the TAR office is closed nights, weekends and holidays, and in emergencies,—and the chilling effect of this retroactive denial, is described by Dr. Lackner, (233-236); "hundreds and hundreds of denied days," (RT 235); and RT 242-243, 245. Also, Joan Vaughan, San Francisco TAR administrator, judicially admitted as part of the State's case-in-chief, that the TAR office "second guesses" the doctor on emergency admissions. (RT 308). ("The Court: So you won't pay the doctor, and you won't pay the hospital? The Witness: That's right." RT 308). And RT 303: "The Court: [A]fter the emergency is over, then they have to get the money, they to have a TAR approval? The Witness: They have to have a certification, and that is done on a TAR form."

Non-Formulary drugs cannot be readily obtained by the TAR system, causing physicians to prescribe contra-indicated non-Formulary drugs for lack of ability to obtain the drug of treatment choice. (Findings 17, 15, CT 464, 463, Appendix E, pp A-53-A-54), which results in among other things, an 8-times higher per use of codeine for Medi-Cal recipients than anywhere else in the country. (Finding 14, CT 462-463, Appendix E, p A-52).

Typical examples of medical judgment, "second-guessing by Medi-Cal "Consultants", cancelling the treating physician's judgment of medical necessity, were also evidenced:

Lorna Purkey, plaintiff: Finding 36, CT 476, Appendix E, p A-61:

> "In her case, she received left masectomy May 11, 1982. Her physician found that it was medically necessary for her to have restorative breast surgery, scheduled for August 1982. The TAR was denied August 17, 1982 on the ground that a 6 to 9 month period should elapse. (This decision was illegal, inasmuch as it overruled the judgment of the treating physician re medical necessity for the procedure.) The provider's appeal letter to the Field Office Administrator on September 6, 1982, was denied on the ground that the § 14133.3 limitation precluded coverage."

Stephen Cowan, plaintiff: Finding 41, CT 477, Appendix E, p A-62:

> "He has a congenital hole [in] his heart, . . . subjecting him to rapid prejudicial symptoms from otherwise ordinary respiratory ailments. Dr. Lackner, who examined him, testified, and the Court finds, that Sudafed is medically necessary for daytime use as prescribed."

COWAN testified that a TAR for *prescribed* Sudafed was denied. (RT 79-81).

Don Bush, a quadraplegic, testified that he has a kidney and bladder infection, (RT 168). His treating urologist Dr. Gobel informed him the bacteria growth was out of hand, and prescribed Macrodantin because the Formulary drug, Nitrofurantoin, could not be tolerated, (RT 170); but this Macrodantin TAR was

denied by Medi-Cal in October 1982, (RT 169-170). At this point Dr. Gobel announced he would no longer treat the patient because "it was too much paperwork, too many phone calls . . . and he did not care to treat me any longer because of the procedures." (RT 171). The condition worsened, resulting in blood clots and a prescription for non-Formulary antibiotics,—which the patient paid for. (RT 172). The patient found a new, clinic doctor who was able to obtain a TAR approval for Macrodantin on January 20, 1983, (RT 175),—(three months after the treating physician first prescribed Macrodantin as medically necessary!).

Penolepe Fitzpatrick, a paraplegic: In 1980, she had a stroke, and her doctor prescribed Cytomel and Clinoril, (because she could not tolerate the Formulary drugs, Motrin, Indocin, Zomax; Robaxinal and Synthroid), (RT 65-67); she was taken off Synthroid because while on it she suffered another stoke, (RT 67); she has always paid for these non-Formulary drugs because her doctor told her Medi-Cal will not pay for them, and because Medi-Cal denied a TAR for Cytomel submitted by the doctor in 1980, "telling them I could not tolerate Synthroid." (RT 69-70).

Other typical samples are strewn through Dr. Lackner's testimony, as for example at RT 225-227.

> "The Court finds that the TAR system, inherently, and *as it presently exists,* takes control of treatment away from the physician, (RT 228-231).

(Finding 30, CT 473, Appendix E, p A-59, emphasis supplied), and that accordingly:

> " . . . Sec. 14133(a) . . . (is) unreasonable and wholly inconsistent with the mandate of the Medicaid Act that treating physicians, not the State, make the determination of what treatment (and drugs) are proper and 'medically necessary' for the needy, and hence contrary to the Medicaid Act, and therefore, illegal and void." (Finding 32, CT 474, Appendix E, p A-59).

* * * * *

ARGUMENT

I. "Second guessing" of the treating physician's determination of medical necessity, both by prior authorization and by post-service review of medical necessity, violates the Medicaid Act requirement that physicians, not the State, determine what treatment and drugs are proper and medically necessary for the needy eligible recipient.

In *Beal v. Doe*, supra, 432 U.S. at 448, a Pennsylvania Medicaid statute required two physicians,—other than the treating physician,—to examine and certify that abortion is a medical necessity. The Supreme Court remanded, holding:

> "On this record, we are unable to determine the precise role played by these two additional physicians, and consequently we are unable to ascertain whether this requirement interferes with the treating physician's medical judgment in a manner not contemplated by Congress."

The concurring opinion noted that:

> " . . . significantly, the Senate Finance Committee Report on the Medicaid bill expressly stated that the 'physician is to be the key figure in determining utilization of health services.' S.Rep.No. 404, 89th Cong., 1st Sess., 46 (1986). Thus the very heart of the congressional scheme is that the physician and patient should have complete freedom to choose the medical procedures for a given condition which are best suited to the needs of the patient." (*Beal v. Doe*, supra, 432 U.S. at 450, 97 S.Ct. at 2374).

Indeed, the Joint Conference Report also so states, adding:

> "The committee's bill . . . provides that it is a physician who is to decide upon admission to a hospital, order tests, drugs and treatments, and determine the length of stay. For this reason the bill would require that payment could be made only if a physician certifies to the medical necessity of the services furnished . . . . " (1965 U.S. Code Cong. and Adm. News, p 1987).

And, the Joint Conference Report states, in respect to utilization review, that:

> "The committee is particularly concerned that the utilization and review function is carried out in a manner which protects the patients . . .
>
> . . .
>
> . . . State agencies could provide consultative services to assist in the establishment of utilization review procedures and in evaluating their effectiveness . . . . " (1965 U.S. Code Cong. and Adm. News, pp 1987-1988);

i.e., Congress clearly intended that a state Medicaid agency *not* make the decisions concerning medical necessity and choice of treatment or prescription.

Then, *Pinneke v. Preisser* (8th Cir.1980) 623 Fed.2d 546, 550, holds flatly that:

> "The decision of whether or not certain treatment or a particular type of surgery is "medically necessary" rests with the individual recipient's physician and not with clerical personnel or government officials."

Pinneke also held:

> "The legislative history also supports the conclusion that Congress intended medical judgments to play a primary role in the determination of medical necessity. S.Rep. No. 404, 89th Congress, 1st Sess., reprinted in (1956) U.S. Code Cong. & Adm. News, pp 1943, 1986-89." (623 Fed.2d at 549).

The Medicaid Act was part of the same bill as the Medicare Act, Title XVIII, and a common interpretation is to be given both titles. (*Beal v. Doe,* supra, 432 U.S. at 450, 97 S.Ct. at 2374; *Roe v. Norton* (1975) 522 Fed.2d 928, 940). (*Preterm, Inc. v. Dukakis,* (1st Cir. 1979), 591 Fed.2d at 125, holds that,—after the State has made its "macro-decision" of what services are covered by the State's plan,—that it is the physician who makes the "micro-decision";

> " . . . that the condition of his patient warrants the administering of a type of medical assistance which that plan makes available." (591 Fed.2d at 127).)

McRae v. Califiano (D.C.N.Y.1980) 491 F.Supp. 630, (reversed on other grounds, 448 U.S. 297, 65 L.Ed.2d 784), emphatically held that interference by the State with the treating physician's judgment of medically necessary treatment, violates the Medicaid Act:

> "The medicaid eligible woman who is pregnant, has a statutory entitlement to medical assistance, and, . . . her entitlement extends to receiving the medical treatment appropriate to her medical problem, the treatment which is recommended by her attending physician's judgment." (491 F.Supp. at 737).

Accordingly, it is clear that the trial court's Judgment that the prior authorization statute, Sec. 14133, on its face, and as implemented, violates the Medicaid Act, was correct and that the Court of Appeal decision must be reversed.

II. The Court of Appeal decision failed to consider a halfway house position in re the prior authorization system, namely, that the State may have *limited authority* only to review the treating physician's determination of medical necessity

Rush v. Parham II, (5th Cir. 1980) 625 Fed.2d 1150, takes the halfway house position that,—albeit recognizing that Congress intended that the physician "be the key figure in determining utilization of health services," (625 Fed.2d at 1157),—that nevertheless the State may make a very limited review of medical necessity, namely, a review to determine if there is "no basis in fact" for the doctor's judgment of what the prescribed treatment shall be:

> "Under these circumstances, we think defendants would have been limited to determining whether the doctor's diagnosis, or his opinion that the prescribed treatment was appropriate to the diagnosis, was *without any basis in fact.*" (625 Fed.2d at 1157). (Emphasis supplied).

I.e., *Rush v. Parham II* seems to be saying that the State "consultant" who is presented a TAR request may not reason, "I disagree with the treating physician and disapprove the TAR based on my disagreement," but, instead, but can only deny

payment where reasonable physicians would conclude there was no basis in fact for the treating physician's professional judgment.

Obviously, Sec. 14133 goes far beyond the "no basis in fact" limited review permitted by *Rush v. Parham II.* Hence it is clear that even under *Rush v. Parham II,* that Sec. 14133 patently violates the Medicaid Act by substituting the *independent judgment* of the State TAR consultant, for the professional determination by the treating physician of what treatment or drugs is medically necessary for the patient.

III. (a) The prior authorization system, *as implemented by Medi-Cal in fact,*—violates the Medicaid Act requirement that the treating physician, not the State, make the determination of what treatment and drugs is medically necessary. (b) The prior authorization system,—*as implemented by Medi-Cal in fact,*—frequently causes *covered services* to be unavailable and "is burdensome, onerous, unreasonable and not in the best interests of Medi-Cal recipients," (CT 470-476), and therein (i) violates 42 C.F.R. Sec. 440.230(b) because the delivery of medical services in fact is insufficient in amount, duration and scope to achieve its purpose; (ii) violates 42 U.S.C., Sec. 1396a(a)(19) which requires the State to assure that services offered will be "provided in a manner consistent with simplicity of administration and the best interests of recipients;" and (iii) violates 42 U.S.C., Sec. 1396a(a)(22) which requires standards and methods which assure that medical services are of high quality; and (iv) violates the *Beal v. Doe* requirement that a State plan be "reasonable" and "consistent with the objectives" of the Medicaid Act.

The trial court findings (which were not overruled by the Court of Appeal), compel these conclusions.

IV. The Medi-Cal drug prior authorization system violates the Medicaid Act because it is unreasonable and contrary to the objectives of the Medicaid Act, (Rule of *Beal v. Doe, supra*)

Dodson v. Parham (N.D.Ga.1977) 427 F.Supp. 97, held that the Medicaid Act is violated where a doctor of pharmacy rather

than a physician made the decision in reviewing drug prescriptions for prior approval. The court held it was:

> "... unrealistic for defendants to presume that a doctor of pharmacy is capable of making that type of informed judgment which is necessary to ultimately review any request for prior approval for a drug which the requesting physician in his experience has found to be medically necessary and indicated for a patient with whom he is intimately familiar, and, that the decision must further reflect the practical experience only possessed by one who is skilled in the medical field and perhaps even in certain specialties." (427 F.Supp. at 108).

This flaw invalidated the drug prior approval system in Georgia. Secondly, *Dodson* also held:

> "It is this court's studied opinion that the fatal flaws in the proposed program lie not so much in drugs delisted, but rather in the absence of what this court considers to be a medically sound and effective prior approval system, which would make non-(Formulary) pharmaceuticals available to those who truly need them, in a speedy and efficient manner with the least interference with the relationship of physicians and Medicaid patients and the informed judgment of the patient's physician. Critical to our finding that (the Formulary) taken together with the prior approval system is medically unsound is that the existing approval mechanisms do not contain emergency procedures which would allow physicians to either obtain prior approval on weeknights, weekends and holidays, or alternatively, to allow the attending physician to himself certify the medical need and the emergency situation to assure that his patient will receive perhaps a five-day dosage until prior approval can be obtained. In the absence of such emergency type procedures, there has been competent testimony that hospitalization might be the only alternative, which is certainly more costly to the Medicaid system and disruptive of the individual lives of Medicaid beneficiaries." (427 F.Supp. at 108).

In case at bar, the trial court in the Statement of Decision, (Appendix E, pp A-52-A-60), found that facts concerning the California drug TAR system to be exactly the same, if not worse, than those found to exist in the *Dodson* case.[9] Hence, the California drug TAR system is likewise in clear violation of the Medicaid Act.

V. The present limitation of Medi-Cal coverage to treatment medically necessary to prevent significant illness, alleviate severe pain, protect life, or prevent significant disability, violates the Medicaid Act.

(1) This limitation is unreasonable and inconsistent with the objectives of the Medicaid Act, (*Rule of Beal v. Doe*, 432 U.S. 438, 444, 53 L.Ed.2d 464, 97 S.Ct. 2364, 2371).

(2) This limitation arbitrarily denies and reduces the amount, duration and scope of Required Services solely because of the diagnosis, type of illness and condition, (namely, conditions which are not a "significant" illness, a "significant" disability, life-threatening, or causing "severe" pain), in violation of 42 C.F.R. 440.230(c);

(3) A standard of treatment with these limitations is insufficient in amount, duration and scope to reasonably achieve its purpose, in violation of 42 C.F.R. 440.230(b).

Plaintiffs welcome and quote the dissenting opinion of Associate Justice Blease in case at bar:

> "The dispositive question is—what is the *federal* definition of 'medical necessity'?—for that is what is binding upon the states and hence upon the Legislature and the physician alike. The short answer is that the federal statute provides a definition in Ttl. XVIII (42 U.S.C. Sec. 1395y(a)(1)(A)), which has consistently been equated with 'medical necessity'

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[9] The bald statement by the Court of Appeal in case at bar, namely, that both treatment and drugs may be provided in emergencies in the California Medicaid system, and, that the provider may get "retroactive authorization", (Appendix A, p A-19), is clearly contrary to both the trial court findings and the trial evidence prior described in this brief.

> in the federal case law. It provides that a service is 'medically necessary' if it is 'reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member . . . ' This controlling definition is facially at odds with the more restrictive California law, which, perforce, must give way." (Dissenting opinion, p 56, Appendix A, p A-24).

Plaintiffs also adopt the supporting argument of Associate Justice Blease on this issue. (Dissenting opinion, Appendix, Exhibit A, pp 56 et seq.)

Plaintiffs note that the issue of the duty of a participating State to furnish all medically necessary services was first considered in *Beal v. Doe* (1977), supra, 432 U.S. at 444-445, 97 S.Ct. at 2371, 53 L.Ed.2d 464. The Supreme Court construed 42 U.S.C. Secs. 1396 and 1396a(a)(17), the latter statute providing:

> "A state plan for medical assistance must—include reasonable standards . . . ".

The Court held that this provision required that:

> " . . . such standards be 'reasonable' and 'consistent' with the objectives of the Act."

(Plaintiffs call this the Rule of *Beal v. Doe.*)

The Supreme Court went on to hold:

> "(A)lthough serious statutory questions might be presented if a state medical plan excluded necessary medical treatment from its coverage, it is hardly inconsistent with the objectives of the Act for a state to fund unnecessary—though perhaps desirable—medical services." (*Beal v. Doe*, supra, 432 U.S. at 444-445, 97 S.Ct. at 2371).

Doe v. Busbee (N.D.Ga.1979) 471 F.Supp. 1326, (summary judgment granted, 481 F.Supp. 46, 49-50), holds flatly:

> "In summary, Title XIX and the regulations promulgated thereunder require that, as a minimum, a state plan for medical assistance must provide for all medically necessary services . . . which fall within the five general categories set out in Title XIX, 42 U.S.C. Sec. 1396d(a)(1)-(5)."

Doe v. Busbee then emphasizes:

> "Title XIX does not explicitly mandate that all medically necessary services be provided by a state plan, however, this Court does find such a mandate in the promulgation of ((what is now 42 C.F.R. 440.230(d))), which provides that a state "*may place appropriate limits on a service based on medical necessity.*" Thus, a state may permissibly discriminate in its provision based on *degrees of need, but only within that range of degree of need which exceed the level of medical necessity.*" (471 F.Supp. at 1330, fn.) (Emphasis supplied).

The importance of this concept, in understanding the Medicaid Act and its requirements, cannot be overemphasized. I.e., 42 C.F.R. 440.230(d), authorizing appropriate limits "based on medical necessity," is *not* a blank check to legislatures and interpreting courts to justify discriminating between recipients having "greater" rather than "lesser" need for medically necessary services. Rather, the "appropriate limits based on medical necessity" clause is a floor,—that which is medically necessary,—beneath which legislatures cannot scrape in their greed to save taxpayers dollars.

Cases which hold that a state Medicaid plan must furnish all medically necessary treatment for the Required Services include: *Rush v. Parham I*, 440 F.Supp. 383, (expressly not overruled on this point by *Rush v. Parham II*, 625 Fed.2d 1150, 1156); *Jaffe v. Sharp* (1978) 463 F.Supp. 222, 229; *Pinneke v. Preisser* (8th Cir.1980) 623 Fed.2d 546, 550; *Roe v. Casey* (1978) 464 F.Supp. 487, 501, (reversed on other grounds, 623 Fed.2d 829, 833); *Roe v. Ferguson* (S.D.Ohio 1974) 389 F.Supp. 387, (reversed on other grounds, 515 Fed.2d 279).

Right to Choose v. Byrne (N.J.1979) 398 A.2d 587, held:

> " . . . the obligation of participating states under 42 U.S.C.A. Sec. 1396 et seq. is to provide Medicaid funding for all necessary medical services . . .",

citing *Roe v. Casey, supra; Emma G. v. Edwards* (E.D.La.1978) 434 F.Supp. 487; *Smith v. Ginzburg*, (S.D.W.Va. 5/9/78) No. 75-0380 CH.

Smith v. Vowell (W.D.Tex 1974) 379 F.Supp. 139, 156:

> "In other words, the State will only furnish ambulance transportation if the patient is to be admitted . . . ; but they will not take him home afterwards. The State's policy totally ignores the concept of remedial, supportive and preventive treatment for the chronically ill, and is shortsighted in the extreme for those so chronically afflicted. Thus untreated, the minor medical problem becomes the major medical problem, . . . ". (379 F.Supp. at 156, affirmed 504 Fed.2d 759).

Also, see *Doe v. State Dept. of Public Welfare* (Minn.1977) 257 N.W.2d 816, 819; *Marsh v. Commonwealth* (Penn.) 409 A.2d 926.

A second line of cases has held that a state legislature may make a "macro-decision" that "only certain kinds of medical assistance are deemed sufficiently necessary to come under the coverage of its plan," (*Preterm, Inc. v. Dukakis* (1979) 591 Fed.2d 121, 125). Such legislative "macro-decisions," however, have the burden of showing that they are "reasonable" and "consistent with the objectives of the Act." (Rule of *Beal v. Doe*). Thus, *Preterm, Inc.*, supra, applying the Rule of *Beal v. Doe,* found that a legislative limitation of abortion to situations where the "life of the mother would be endangered" was:

> " . . . based on medical condition involved rather than on a determination of medical necessity." (591 Fed.2d at 126).

To boot, the limitations of Medi-Cal coverage, contained in Secs. 14059.5 and 14133.3 (as amended), clearly violate 42 C.F.R. 440.230(c), in that the limitations so specified are based on diagnosis, type of illness and condition, contrary to the requirement that:

> "The Medicaid agency may not arbitrarily deny or reduce the amount, duration or scope of a required service . . . solely because of the diagnosis, type of illness or condition."

Also, the "macro-decision" of the California Legislature, in enacting Secs. 14059.5 and 14133.3 (as amended), is not confined to "that range of degree of need which exceed the level of medical necessity," as required by *Doe v. Busbee*, supra, 471 F.Supp. at 1330, and hence, these statutes violate 42 C.F.R. 440.230(d) on that account.

Also, 42 C.F.R. 440.230(b) requires that:

> "Each service must be sufficient in amount, duration and scope to reasonably achieve its purpose."

It is obvious that medical and drug services which *exclude* conditions which are slightly disabling or which constitute a "slight" illness, or which cause only "non-severe pain," are insufficient in amount, duration and scope to reasonably achieve their purpose of providing medical assistance to eligible individuals in need of treatment and unable to pay for it. (*Preterm Inc. v. Dukakis*, supra:

> "The Medicaid system was established for the purpose of enabling a state, with federal participation, to provide medical assistance to eligible individuals in need of treatment and unable to pay for it. See 42 U.S.C. 1396." (591 Fed.2d at 126).)

REASONS FOR ALLOWING THE WRIT

From the standpoint of Rule 17, Rules of the U.S. Supreme Court, petitioners note that the Questions Presented for Review were decided by the Court of Appeal,—a state court of last resort,—contrary to every applicable decision of the U.S. Supreme Court and federal courts of appeal, namely: *Beal v. Doe* (1977) 432 U.S. 438, 448-454, 53 L.Ed.2d 484, 97 S.Ct. 2364, 2373-2376; *Pinneke v. Preisser* (8th Cir.1980) 623 Fed.2d 546; *Rush v. Parham II* (5th Cir. 1980) 625 Fed.2d 1150; and *Preterm, Inc. v. Dukakis* (1st Cir.1979) 591 Fed.2d 121; and *Doe v. Kenley* (4th Cir.1978) 584 Fed.2d 1362, 1363.[10] And, in any

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[10] Indeed, the Court of Appeal decision is contrary to every federal court decision upon these subjects, as shown previously in this petition.

event, the Questions Presented for Review are important questions of federal law which should be settled by the U.S. Supreme Court, particularly in view of the fact that California's 3 million Medicaid recipients, (who are being denied Medicaid rights under the Court of Appeal decision), comprise approximately 1/7th of all Medicaid recipients in the country.

How many millions of Medicaid recipients, impaired by an erroneous court of appeal decision, does it take to constitute an important question of federal law? Petitioners believe that 3 million affected Medicaid recipients is quite more than enough. Also, this is an era of fiscal pinch-millions in state government. If California can escape Medicaid duties, as it so far has done in the case at bar, other states will also so attempt, and, then, what rules will courts in those states apply? The erroneous rules of *Cowan v. Myers*, or, the rules laid out by all federal courts to date which have considered these issues? In sum, implementation of the Medicaid Act, as a federal system, at the level and with the procedures required by Congress, is destroyed unless the United States Supreme Court acts in this case.

WHEREFORE, petitioners pray that the United States Supreme Court grant, allow and issue its writ of certiorari, directed to the Court of Appeal of the State of California, Third Appellate District, and thereupon to review and reverse the December 9, 1986 decision in *Cowan et al. v. Myers et al.*, 187 Cal.App.3d 968, together with such other relief as the Court may deem proper, together with costs of suit incurred.

LYNN S. CARMAN
Counsel for Petitioners

INDEX TO APPENDIX

Appendix A

Certified for Publication

In the Court of Appeal of the State of California
in and for the Third Appellate District
(Sacramento)

3 Civil 22987
(Super. Ct. No. 308404)

Stephen Cowan, et al.,
Plaintiffs and Appellants,

vs.

Beverlee A. Myers, as Director, etc., et al.,
Defendants and Appellants.

DECISION

[Filed Dec. 9, 1986]

APPEAL from the judgment of the Superior Court of Sacramento County. William W. White, Judge. Reversed in part.

At issue in this appeal are certain provisions of the Medi-Cal Benefits Program (Welf. & Inst. Code, § 14000 et seq.), which limit health services to those "medically necessary to protect life or prevent significant disability" and whether such provisions are fatally inconsistent with the Federal Medicaid Act (the Act). (42 U.S.C. § 1396 et seq.) The trial court found this limitation would unduly curtail medical assistance to the poor, contrary to the objectives of the Act and further found the system of prior authorization for health services, designed to implement the definition of medical necessity, was inconsistent with the Act. (Welf. & Inst. Code, § 14133.3, prior to 1985 amendment ch. 1411, § 2.) A writ of mandate issued from the trial court ordering the defendant state agencies and officials to refrain from enforcing either the limitation on medically necessary services or the prior authorization system.[1]

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[1] Inexplicably, neither the judgment entered by the trial court nor the writ of mandate issued by the clerk of the court is part of the formal record on appeal. However, copies of each are included in the petition

These state agencies and officials (hereafter collectively the State) appeal, contending: (1) the plaintiffs failed to exhaust their administrative remedies; (2) the definition of medical necessity in the Medi-Cal Benefits Program is consistent with federal law; and (3) the prior authorization program is likewise consistent with federal law. The plaintiffs have cross-appealed, contending the judgment erroneously failed to restrain a postservice system of authorization of Medi-Cal services.

During the pendency of this appeal the Legislature amended several Medi-Cal provisions and expanded the definition of medically necessary services. (§ 14059.5.)[2] The version of Medi-Cal provisions presently in force is the relevant legislation for this appeal as "on appeals from judgments granting or denying injunctions, the law to be applied is that which is current at the time of judgment in the appellate court." (City of Whittier v. Walnut Properties, Inc. (1983) 149 Cal.App.3d 633, 640, citing Kash Enterprises, Inc. v. City of Los Angeles (1977) 19 Cal.3d 294, 306, fn. 6.) The principal question on this appeal now is whether the amended provisions, which currently limit health services to those "medically necessary to prevent significant illness, to alleviate severe pain, to protect life, or to prevent significant disability," are fatally inconsistent with the Act. (42 U.S.C. § 1396 et seq.)

We conclude the Medi-Cal statutes are in compliance with federal law, but that current regulations governing medical coverage do not conform to those Medi-Cal statutes. This conclusion renders the cross-appeal moot and requires partial reversal of the judgment.

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for supersedeas filed by the State on June 15, 1983. We take judicial notice of those records. On June 17, 1983, this court granted the petition of supersedeas staying enforcement of the trial court's judgment and all further proceedings thereon pending resolution of this appeal. The writ issued September 16, 1983, and remains in effect.

[2] Hereafter, all unspecified statutory references are to sections of the Welfare and Institutions Code.

FACTS

The Medi-Cal Benefits Program as originally enacted provided for benefits covering outpatient services, hospital services, nursing services, certain drugs, medical transportation, and home health care services among others. (See former Welf. & Inst. Code, § 14132.) In 1975, section 14132 was amended, and the provision of most health services was made "subject to utilization controls." (Stats. 1975, ch. 1005, § 3, subd. (b), p. 2360.) These controls on the utilization of Medi-Cal services were set out in section 14133.[3] The controls allowed the State to withhold coverage or payment for services which were determined to be medically unnecessary. The 1975 provisions did not define a "medical necessity."

In 1982, the Legislature enacted section 14133.3. This section defined the term "medical necessity" as used in relation to the established utilization controls. Section 14133.3 at that time provided in relevant part: "(a) The director shall require fully documented medical justification from providers that the requested services *are medically necessary to protect life or prevent significant disability*, on all requests for prior authorization. [¶] (b) For services not subject to prior authorization, the director shall additionally determine utilization controls which shall be applied to assure that the health care services provided and the conditions treated, *are medically necessary to protect life or prevent significant disability*. Such utilization controls shall take

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[3] The three relevant types of controls are: (1) "Prior authorization, which is approval by a [State Department of Health] consultant, of a specified service in advance of the rendering of that service based upon a determination of medical necessity"; . . . [¶] (2) "Postservice prepayment audit, which is review for medical necessity and program coverage after service was rendered but before payment is made. Payment may be withheld or reduced if the service rendered was not a covered benefit, deemed medically unnecessary or inappropriate"; . . . [and] [¶] (3) "Postservice postpayment audit, which is review for medical necessity and program coverage after service was rendered and the claim paid. The department may take appropriate steps to recover payments made if subsequent investigation uncovers evidence that the claim should not have been paid." (§ 14133, subds. (a), (b), (c).)

into account those diseases, illnesses, or injuries which require preventive health services or treatment to prevent serious deterioration of health." (Italics added.) The Legislature also determined to remove certain drugs from the "Medi-Cal Drug Formulary," a list of drugs for which no prior authorization is needed and to eliminate coverage for various "common medicine chest medical supply items, over-the-counter drug products, prescription drug products which afford minor symptomatic relief, and codeine and other narcotic analgesics." (Stats. 1982, ch. 328, § 53, subd. (2), p. 1606.) These statutory changes led to revisions in the Medi-Cal regulations, which limited health care services to those "which are reasonable and necessary to protect life or prevent significant disability, . . ." (Cal. Admin. Code, tit. 22, § 51303, subd. (a).)[4]

On or about September 1, 1982, the State sent a letter to all Medi-Cal recipients detailing the changes in Medi-Cal benefits. The letter stated in part: "Coverage of medical, surgical, and other services will be limited to only those services which are considered medically necessary to protect life or prevent significant disability. Those elective services which can be eliminated without seriously endangering your life or causing you a significant disability will no longer be approved. . . . If you are denied a service and your condition worsens to the point where further denial would endanger your life or cause significant disability, the

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[4] For example, subdivision (a) of section 51303 of title 22 of the California Administrative Code provides in relevant part: "Health care services set forth in this article . . . which are reasonable and necessary to protect life, to prevant significant illness or significant disability, or to alleviate severe pain through the diagnosis or treatment of disease, illness or injury are covered by the Medi-Cal program, subject to utilization controls, . . . Such utilization controls shall take into account those diseases, illnesses, or injuries which require preventive health services or treatment to prevent serious deterioration of health." Similarly, title 22, California Administrative Code, section 51305, subdivision (a) provides: "Outpatient physician services are covered if they are medically necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain, subject to the limitations specified below."

service can be reconsidered for approval." The letter detailed certain drug program reductions and listed a number of drugs which would be covered only after prior authorization.

The plaintiffs are three Medi-Cal recipients and one resident taxpayer of California. They alleged that because of the Medi-Cal changes they were not receiving health services which were medically necessary, but were not necessary to protect life or prevent significant disability. They sought to mandate to restrain the State from enforcing the new restriction on Medi-Cal services and to require the State to pay for all drugs, procedures, and services prescribed by physicians without the necessity of prior authorization. The trial court granted the relief requested. The State sought reconsideration on two grounds. First, the State informed the trial court that the Medi-Cal amendments had been approved by the federal Department of Health and Human Services as being in compliance with the Act. Second, the State proffered new evidence that one of the plaintiffs, Lorna Purkey, had successfully completed an administrative appeal, resulting in a granting of the treatment the petition alleged had been denied her. The State contended this rendered significant portions of the case moot. The motion for reconsideration was denied, and judgment granting a peremptory writ of mandate was entered. This appeal followed.

Thereafter, the Legislature enacted section 14059.5, which provides: "A service is 'medically necessary' or a 'medical necessity' when it is reasonable and necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain."

The State first contends the trial court lacked jurisdiction to entertain the instant petition because the plaintiffs failed to allege exhaustion of the appropriate administrative remedies. This contention would have some merit if plaintiffs were simply challenging the denial of Medi-Cal benefits. In such circumstances, the right to an administrative appeal hearing is clear. (§ 10950; Cal. Admin. Code, tit. 22, § 50951 et seq.) In fact, the record discloses that subsequent to trial the treatment requested by plaintiff

Purkey was granted through just such an administrative appeal.[5] The denial of benefits, however, was not the only grievance raised by the petition. The plaintiffs also alleged the relevant Medi-Cal statutes and regulations were violative of federal law. "An administrative agency . . . has no power: [¶] To declare a statute unenforceable, or to refuse to enforce a statute on the basis that federal law or federal regulations prohibit the enforcement of such statute unless an appellate court has made a determination that the enforcement of such statute is prohibited by federal law or federal regulations." (Cal. Const., art. III, § 3.5, subd. (c).) Moreover, the same code section which granted plaintiffs an administrative appeal to contest the denial of Medi-Cal benefits provides: "there is no right to a state hearing when . . . the sole issue is a federal or state law requiring an automatic change in services or medical assistance which adversely affects some or all recipients." (§ 10950.) As the eventual granting of benefits to two of the plaintiffs renders their denial of benefits claim moot, the sole issue remaining as to them is the validity of the relevant statutes and regulations. Plaintiffs correctly contend any attempt to exercise an administrative remedy on this issue would be inadequate, thus making the exhaustion requirement inapplicable. (Glendale City Employees' Assn., Inc. v. City of Glendale (1975) 15 Cal.3d 328, 342.) While the plaintiffs in this case may no longer have a direct grievance with the State (i.e., the denial of Medi-Cal benefits), the very important question of the validity of the Medi-Cal coverage restrictions remains alive both as to the taxpayer-plaintiff (Mayer) and to Medi-Cal recipients in general. (See Grier v. Alameda-Contra Costa Transit Dist. (1976) 55 Cal.App.3d 325, 330.) We conclude the present appeal is properly before this court and is barred neither by mootness nor the failure to exhaust administrative remedies.

II

The State next asserts the trial court erred in finding the definition of "medically necessary" services in Welfare and Insti-

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[5] The record also reveals that plaintiff Cowan's request for authorization of certain drugs was also approved.

tutions Code section 14133.3, now replaced by a similar but broader definition in section 14059.5, conflicted with the Act.[6] We perceive the fundamental question presented by this contention to be the crux of the appeal: Who decides what Medi-Cal services qualify as "medically necessary," the physician or the State? We conclude plaintiffs are in error when they assert the physician is the sole arbiter of what constitutes a medical necessity. The Act permits the states discretion to determine on the basis of need which services shall be provided as part of the Medicaid program. The current California definition of medical necessity in section 14059.5 like its predecessor in section 14133.3, is a proper limitation on services, within the discretion provided by the federal law. We therefore reverse the judgment of the trial court insofar as it held otherwise.[7]

A

We first examine the Act. One of its express purposes is to enable "each state, as far as practicable under the conditions in such state, to furnish medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services. . . ." (42 U.S.C. § 1396.) To accomplish this purpose, the Act appropriates funds to make payments to states with plans for medical assistance which have been

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[6] In 1985, the Legislature also amended section 14133.3 to conform to section 14059.5, insofar as the latter defines "necessary medical services."

[7] Plaintiff's appellate brief divides the trial court's ruling into six separate "judgments," which it asserts must all be affirmed. (E.g., "Judgment Two must be affirmed . . . .") Plaintiffs should be aware there is but one final judgment in an action, which finally determines the rights of parties in relation to the matter in controversy. (Code Civ. Proc., § 577; Maier Brewing Co. v. Pacific Nat. Fire Ins. Co. (1961) 194 Cal.App.2d 494, 497.) This error merits comment in light of counsel's berating of the State's legal argument as "shallow," "a joke" and "frivolous." Such hyperbole is unbecoming where one's own argument is less than paradigmatic.

submitted to and approved by the Secretary of Health and Human Services. (*Ibid.*) The Act requires participating states to provide qualified individuals with financial assistance in five general categories of services: (1) inpatient hospital services; (2) outpatient hospital services; (3) laboratory and X-ray services; (4) skilled nursing facility services; and (5) physician services. (Beal v. Doe (1977) 432 U.S. 438, 440-441 [53 L.Ed.2d 464, 469-470].) "Although [the Act] does not require States to provide funding for all medical treatment falling within the five general categories, it does require that state Medicaid plans establish 'reasonable standards . . . for determining . . . the extent of medical assistance under the plan which . . . are consistent with the objectives of [the Act].' " (*Id.*, at p. 441.) "This language confers broad discretion on the States to adopt standards for determining the extent of medical assistance, requiring only that such standards be 'reasonable' and 'consistent with the objectives of the Act.' " (*Id.*, at p. 444.)

The parties appear to agree that a state plan may limit services to those which are "medically necessary."[8] They disagree over who decides which services qualify as medically necessary. The trial court adopted plaintiffs' position that "[t]he spirit of the Medicaid Act is that *physicians* make the decision of whether or not certain treatment is 'medically necessary.' " Support for this position is found in Pinneke v. Preisser (8th Cir. 1980) 623 F.2d 546, 550, wherein it was stated: "The decision of whether or not certain treatment or a particular type of surgery is 'medically necessary' rests with the individual recipient's physician and not with clerical personnel or government officials." The sweep of this language is less broad than it would seem, however, when considered in the context in which it was made. In *Pinneke*, the plaintiff underwent sex reassignment surgery and applied for funding under the Iowa Medicaid program. Funding was denied because Iowa's Medicaid program specifically excluded coverage for sex reassignment surgery. (*Id.*, at p. 547.) The court noted this

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[8] This conclusion is inescapable. The federal Medicaid regulations provide: "The [Medicaid] agency may place appropriate limits on a service based on such criteria as medical necessity or utilization control procedures." (42 C.F.R. § 440.230(d).)

amounted to an irrebuttable presumption that sex reassignment surgery can *never* be "medically necessary," even though it may be the *only* treatment for a condition of transsexualism. (*Id.*, at pp. 548-549.) As the Medicaid regulations prohibit discrimination on the basis of medical condition, the court held the procedure fell into both " 'inpatient hospital services' " and " 'physicians' services' " which the state plan had agreed to provide. (*Id.*, at p. 550.)

Pinneke does not stand for the proposition that the physician is the sole arbiter of medical necessity. Rather, it holds that once a state plan has agreed to cover certain types of services, it may not exclude covered services for one particular *condition* where the physician determines the treatment is necessary. *Pinneke* illustrates that there are in fact two levels of medical necessity inherent in the Medicaid scheme. First, the state must decide which *services* are necessary; then, out of the covered services, the physician may determine which *treatment* is necessary for a particular condition. This two-part test was expressed in Preterm, Inc. v. Dukakis (1st Cir. 1979) 591 F.2d 121.) In that case, the court considered dicta in *Beal v. Doe*, supra, 432 U.S. at pages 444-445, that "serious statutory questions might be presented if a state Medicaid plan excluded necessary medical treatment from its coverage, . . . " The *Preterm* court held: "[W]e do not believe that we should read this dictum as signalling a flat rule that all services within the five general categories deemed 'medically necessary' by a patient's physician must be provided by the state plan. [¶] Such a reading, permitting the most varied content to the words 'necessary medical services', the variations being theoretically limited only by the diversity of physicians, would seem at war with the goals of consistency and fairness in the administration of the statute. We see two levels of judgment as to medical necessity in the statutory scheme. The first is the macro-decision by the legislature that only certain kinds of medical assistance are deemed sufficiently necessary to come under the coverage of its plan. The second is the micro-decision of the physician, that the condition of his patient warrants the administering of a type of medical assistance which that plan makes available." (Preterm, Inc. v. Dukakis, supra, 591 F.2d at p. 125.) In *Preterm* the court was concerned with the "macro-decision" of the Massachussetts

legislature to limit state funding of abortions, in cases other than rape or incest, to those necessary to save the life of the woman. (*Ibid.*) The court concluded this restriction improperly discriminated against a particular condition, a medically complicated pregnancy, by restricting treatment for this condition to life and death situations. (*Id.*, at p. 126.)

In both *Pinneke* and *Preterm*, the state Medicaid plan singled out a specific condition and placed special restrictions on services for that condition. Such discrimination, where the state plan generally provided for the appropriate services and the treating physician felt such services were medically necessary, was held to be violative of the Act in both cases. Both courts relied on 42 Code of Federal Regulations, section 440.230(c), which provides: "The Medicaid agency may not arbitrarily deny or reduce the amount, duration, or scope of a required service . . . to an otherwise eligible recipient solely because of the diagnosis, type of illness, or condition." As pointed out by amicus secretary of Health and Human Services, however, the exclusion of treatment for a specific condition is considerably different from a general exclusion of certain services. Illustrative is Rush v. Parham (5th Cir. 1980) 625 F.2d 1150. *Rush*, like *Pinneke*, was a case involving a denial of funding for reassignment surgery. (*Id.*, at p. 1153.) In *Rush*, however, the reason for denial was that the Georgia Medicaid plan excluded reimbursement for experimental forms of treatment, i.e., treatment not generally recognized as effective by the medical profession. (*Id.*, at pp. 1154-1155.) The court held the state's "responsibility to establish standards extends at least to the shaping of a reasonable definition of medical necessity." (*Id.*, at p. 1156.) "This does not remove from the private physician the primary responsibility of determining what treatment should be made available to his patients. We hold only that the physician is required to operate within such reasonable limitations as the state may impose." (*Ibid.*) The court concluded that Georgia's definition of medically necessary services could reasonably exclude experimental surgery and remanded for a finding as to whether transsexual surgery was experimental. (*Id.*, at pp. 1156-1157.)

At first blush, *Rush* and *Pinneke* appear completely at odds. Sexual reassignment surgery could properly be excluded in the former, but not in the latter. The difference lies in the nature of the two exclusions. In *Bush*, the exclusion for experimental surgery was generic. It did not discriminate against any particular treatment or condition. In *Pinneke*, on the other hand, the exclusion was treatment specific, singling out a particular condition. In the language of *Preterm*, the Legislature in *Rush* made a proper "macro-decision" to exclude certain services from coverage by determining they were not medically necessary. In *Pinneke*, however, the Legislature intruded into the "micro-decision" of the physician by deciding that one particular treatment within the generally covered service of surgery was excluded, even though it might be necessary to treat a specific condition. The two cases can be reconciled in a manner which provides considerable insight into the objectives of the Act. A state may place a generic limit on Medicaid services based upon a judgment as to the degree of medical necessity of those services, so long as it does not discriminate on the basis of the specific medical condition which occasions the need. (Curtis v. Taylor (5th Cir. 1980) 625 F.2d 645, 652.)

Applying this principle to the case at bar, we conclude the limitation of Medi-Cal services to those necessary to protect life, to prevent significant disability or illness, or to alleviate severe pain (§ 14059.5) is consistent with the objectives of the Act. The restriction does not single out any particular condition. It merely represents a legislative judgment that the medical services provided be restricted to those cases where they are most needed. Plaintiffs' contention that Medicaid requires states to provide *all* services within the covered categories which a physician determines are medically necessary is neither correct nor workable.[9] (See Note, *State Restrictions on Medicaid Coverage of Medically Necessary Services* (1978) 78 Colum.L.Rev. 1491, 1498-1502 (hereafter *Medicaid Coverage*).) The Medicaid regulations ex-

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[9] The cases cited by plaintiffs state only that Medicaid requires the provision of all medically necessary services. They do not indicate *who* defines a medical necessity or *how* it is to be defined. (See e.g., Doe v. Busbee (N.D.Ga. 1979) 471 F.Supp. 1326, 1330.)

pressly permit the State to limit services on the basis of medical necessity. (42 C.F.R. § 440.230(d).) We are convinced the Act did not intend the *physician* to be the sole arbiter of medical necessity. Not only would such a rule result in inconsistent and unfair applications based on the variation between physicians (Preterm, Inc. v. Dukakis, supra, 591 F.2d at p. 125), but the State's requirement of reimbursement would be limited only by the imagination of physicians. Such open-ended liability was not the intent of the Act. (See Note, *The Determination of Medical Necessity: Medicaid Funding for Sex-Reassignment Surgery* (1980) 31 Case Western Res.L.Rev. 179, 184-185, 202 (hereafter *Medical Necessity*).) The express purpose of the Act was to enable states to provide health care to the needy "*as far as practicable under the conditions in such State* . . . ." (42 U.S.C. § 1396) (Italics added.) Welfare and Institutions Code sections 14059.5 and 14133.3 represent a proper effort by California to limit Medi-Cal services on the basis of medical necessity.

Both plaintiffs and various welfare rights groups acting as amici curiae urge that even if the Act allows for restrictions on services based on medical necessity, the particular restriction employed by the State in this case is unreasonable. They point out the test in *Beal v. Doe* requires state Medicaid standards to be " 'reasonable' " as well as " 'consistent with the objectives' " of the Act. (Beal v. Doe, supra, 432 U.S. at p. 444.) They urge the Medi-Cal standard is unreasonable because it restricts the provision of necessary health services to life or death situations. The amici welfare rights organizations paint a horrendous picture in which Medi-Cal recipients are routinely denied benefits for painful and contagious disorders because they are not life-threatening. Contrary to plaintiff's urgings, however, our task is not to assess the reasonableness of the *application* of the Medi-Cal standard of medical necessity to any set of facts, real or hypothetical.[10] Rather, the question presented by this case is whether the

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[10] As previously noted, the only two plaintiffs who testified as to a denial of benefits (Cowan and Purkey) were ultimately shown to have received Medi-Cal assistance as requested. The third plaintiff who alleged a denial of benefits (DuPont) did not testify at trial. The remaining petitioner premised his standing on his status as a taxpayer.

Legislature's restriction of Medi-Cal services to those medically necessary to protect life, to prevent significant disability or illness, or to alleviate severe pain, is unreasonable on its face. We answer this question in the negative.

As an initial matter, we are unpersuaded by plaintiffs' doom-saying view that a needy individual would have to be in a life or death situation before Medi-Cal would intervene. Plaintiffs ignore that portion of the previous standard in section 14133.3 which permitted Medi-Cal services when "medically necessary . . . to prevent significant disability." The concept of preventing significant disability encompasses medical intervention at an early stage in a disorder, to *prevent* future disability. (See *Medicaid Coverage*, supra, at p. 1498.) Nothing in either the prior or present definition of medical necessity requires a Medi-Cal provider to stand idly by until a patient is actually disabled by an illness. (*Id.*, at p. 1498, fn. 62.) The opinions of plaintiffs' experts aside, nothing in the record shows the State has denied or will deny Medi-Cal benefits to any eligible individual who demonstrates a medical need which raises a threat of illness or disability.

Plaintiffs rely heavily on 42 Code of Federal Regulations section 440.230(b). That section provides: "Each service must be sufficient in amount, duration, and scope to reasonably achieve its purpose." In arguing that section 14133.3, prior to its amendment in 1985, [11] violated this regulation, plaintiffs assume the "purpose" referred to therein is to provide *all* medically necessary services. We have determined that a state Medicaid plan need not offer all services within the five general categories listed by the Act. (Preterm, Inc. v. Dukakis, supra, 591 F.2d at p. 125.) The regulation cited is not a "content" regulation, i.e., establishing which services must be provided (cf. 42 C.F.R. §§ 440.210, 440.220), but is instead concerned with the *sufficiency* of the services which are provided. Once the state determines to provide a certain type of service, for example X-ray services or dental services, the state must ensure there are adequate resources to

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Thus, whether the restriction was reasonable as applied to any particular Medi-Cal recipient was not an issue before the trial court.

[11] See footnote 6, *ante*.

achieve the purpose of the service. (See *Medicaid Coverage*, supra, at pp. 1501-1516.) In the present case, the purpose of the services provided by Medi-Cal is to provide the needy with medical assistance which is necessary to protect life, to prevent significant disability or illness, or to alleviate severe pain. (§ 14059.5.) So long as the programs provided are sufficient to meet this level of service and achieve this purpose, no violation of 42 Code of Federal Regulations section 440.230(b) will occur. Welfare and Institutions Code section 14059.5 does not violate the federal regulation. It simply establishes the standard by which the sufficiency of any service must be judged.

Finally, and most important, plaintiffs' assertion of the unreasonableness of the State's standard of medical necessity fails to recognize that the federal agency charged with considering and certifying state Medicaid plans *approved* the standard set forth in section 14133.3 prior to its amendment in 1985. The trial court's statement of decision, prepared by plaintiffs, attempts to discount this approval by finding that because the standard is incorporated into the Medi-Cal plan by reference, "[o]ne would have to be especially astute to apprehend from such presentation of the 'State Plan' that physicians' services are drastically curtailed to only those 'medically necessary to protect life of prevent significant disability' ". The record does not support this finding. On *each page* of the "Medi-Cal Benefits Chart" submitted to the Department of Health and Human Services, the heading "Program Coverage" is marked with a double asterisk, which is explained on *each page* as follows: "Coverage is limited to medically necessary services as defined in Section 51303 (a)." Title 22, California Administrative Code section 51303 subdivision (a) provides in part: "Health care services set forth in this article . . . which are reasonable and necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain through the diagnosis or treatment of disease, illness or injury are covered by the Medi-Cal program, subject to utilization controls, . . . " We fail to see how this limitation could have been made plainer, short of printing it in full on every page of the plan submitted to the federal agency. The trial court simply refused to accord the approval of the responsible federal agency the deference it deserved, " '[W]e must be mindful that "the

construction of a statute by those charged with its execution should be followed unless there are compelling indications that it is wrong. . . .' " (Beal v. Doe, supra, 432 U.S. at p. 447.) There are no such indications in this case. California determined to limit its Medi-Cal benefits program on the basis of medical necessity. The Department of Health and Human Services, upon being fairly apprised of the standard to be employed, approved the plan as reasonable and consistent with the objectives of the Act. The trial court erred in finding the Medi-Cal limitation unreasonable.

Moreover, we are convinced it is the formulation of the trial court, leaving the determination of medical necessity soley in the hands of the providers, that is unreasonable. In such circumstances it is the physician who would determine whether he or she should be reimbursed for providing health care. It is not difficult to see what that determination would be in every case. With due respect to the professionals who provide health care services under the Medi-Cal benefits program, The Act never intended to grant these physicians cart blanche to charge services to the State. We conclude the limitation on services in Welfare and Institutions Code sections 14059.5 and 14133.3 is both reasonable and consistent with the objectives of the Act.

III

The State next contends the trial court erred in finding the Medi-Cal system of prior authorization of services violative of the Act. While the prior authorization system applies to all Medi-Cal services, the focus at trial was on the prior authorization as applied to those drugs which were not on Medi-Cal formulary. The trial court found this system "is inconsistent with the mandate of the Medicaid Act that physicians, not the State, make the determination of what treatment (and drugs) are proper and 'medically necessary' for the needy patient." We conclude this finding is in error.

Prior authorization is "approval by a department consultant, of a specified medical service in advance of the rendering of that service based upon a determination of medical necessity." (Welf. & Inst. Code, § 14133, subd. (a).) The primary mechanism for

prior authorization of services is the treatment authorization request ("TAR"). TARs are submitted by physicians in advance of providing the services. They can be submitted either in writing or by telephone. The request is transcribed onto a form (if submitted by telephone) and then given to either a physician or pharmacist, who makes the decision whether to authorize treatment. Not all physician's services or drugs require TARs. In emergencies, the physician may treat the patient first, and then request retroactive authorization.[12] Office visits do not require TARs, while elective hospitalizations do. As for drugs, a TAR is only required if the prescribed drug is not on the Medi-Cal formulary. The processing time for each TAR is one to three days for drugs, and five to seven days for physicians' services.[13]

The State urges the Act and its attendant regulations specifically allow individual states to "place appropriate limits on a service based on . . . utilization control procedures." (42 C.F.R. § 440.230(d); see also 42 U.S.C. § 1396a(a)(30).) The TAR system is simply one type of procedure to control the utilization of Medi-Cal services. (Welf. & Inst. Code, § 14133, subd. (a).) The trial court's principal objection to the TAR system was its inconsistency with the perceived Medicaid mandate that the physician determine what treatment was "medically necessary" for the needy patient. We have already determined the State's restriction on the meaning of medical necessity is proper under

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[12] Title 22, California Administrative Code, section 51003 subdivision (b) provides in relevant part: "Retroactive approval of requests for prior authorization may be granted only under the following conditions: . . . [¶] (3) When communication with the Medi-Cal Consultant could not be established and provision of the required service should not have been delayed; under this condition the request for retroactive authorization must be received by the Medi-Cal Consultant within 10 working days after the service is provided or initiated."

[13] Consistent with the trial court's philosophy that health care providers should be the sole determiners of what is medically necessary, the court found fault with doctors of pharmacy making decisions with respect to drug TAR. This same objection was voiced in Dodson v. Parham (N.D.Ga. 1977) 427 F.Supp. 97, which considered the prior approval plan of the Georgia's Medicaid law.

the Act. It follows that if the State can limit services to situations where they are "medically necessary" as defined, there must be some mechanism by which the State can enforce its definition. That prior authorization is a permissible utilization control is shown by the approval of this system by the secretary of Health and Human Services. In fact, the system of prior authorization has been in place since 1975. (See Stats. 1975, ch. 1005, § 2, p. 2359, § 5, p. 2362.) Plaintiffs' real objection is not to the concept of prior authorization, but to the fact the 1982 Medi-Cal amendments greatly increased the number of services and drugs subject to prior authorization. Conceding the TAR system may be less convenient for health care providers, does this inconvenience render the system violative of the Act? The answer is "no."

In Margulis v. Myers (1981) 122 Cal.App.3d 335, we considered the application of prior authorization controls to all Medi-Cal services provided by a particular physician who engaged in an unusual type of practice.[14] The physician contended it was improper to impose the requirement of prior authorization without first giving him a hearing. This court upheld the prior authorization order. We first noted the pertinent federal regulations required that the state Medicaid agency " 'must create a statewide surveillance and utilization control program that—[¶](a) Safeguards against unnecessary or inappropriate use of Medicaid services and against excess payments; . . . [and] [¶] (c) Provides for the control of the utilization of all services provided under the plan . . . .' " (*Id.*, at p. 340; see 42 C.F.R. § 456.3.) In holding that the physician was not entitled to a hearing before implementation of the prior authorization order, we reasoned that "[a]lthough prior authorization inconveniences appellant it is applied not as a penalty, *but as a means by which the department ensures that only necessary services are provided.*" (Margulis v. Myers, supra, 122 Cal.App.3d at p. 342.) (Italics added.) Im-

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[14] Although the physician maintained regular office hours, the majority of his Medi-Cal claims were for house calls occurring during the evenings and on weekends. Further, numerous claims were for persons of the same surname rendered weekly over a period of years. The diagnoses for these repeated visits amounted to repetitious cases of a common cold. (Margulis v. Myers, supra, 122 Cal.App.3d at pp. 338-339.)

plicit in the *Margulis* holding is the conclusion that prior authorization is a permissible method of ensuring that Medi-Cal services are limited to those defined as medically necessary. We see no reason to deviate from that conclusion in the present case.

Nothing in Dodson v. Parham, supra, 427 F.Supp. 97 compels a different result. Plaintiffs incorrectly assert "*Dodson v. Parham* controls this judgment." As an initial matter, the decisions of the lower federal courts, even on federal questions, are not binding on this court. (People v. Bradley (1969) 1 Cal.3d 80, 86; Debtor Reorganizers, Inc. v. State Bd. of Equalization (1976) 58 Cal.App.3d 691, 696.) In any event, *Dodson* fails even as persuasive authority, in part because it is factually distinguishable, but also because we find implicit in that decision a standard for assessing prior authorization schemes which, if it were applied to Medi-Cal, would make it impracticable for the department to satisfy the federal mandate of creating a utilization control program that safeguards against unnecessary use of Medicaid services. (42 U.S.C. § 456.3.)

In *Dodson*, the court considered a Georgia Medicaid plan which placed certain drugs on a list or formulary and required prior authorization for those drugs not appearing on the list. The process was very similar to that under consideration in the present case. (Dodson v. Parham, supra, 427 F.Supp. at pp. 100-101.) In 1976, the formulary was reduced in an effort to curb certain excesses and abuses under the former plan. (*Id.*, at pp. 101-102.) The court held the plaintiffs challenging the new list and prior approval system had made sufficient showing to justify a temporary injunction against the new program. (*Id.*, at p. 108.) "Critical to our finding that [the formulary] taken together with the prior approval system is medically unsound is that the existing approval mechanisms *do not contain emergency procedures which would allow physicians to either obtain prior approval on weeknights, weekends, and holidays, or alternatively, to allow the attending physician to himself certify the medical need and the emergency situation* to assure that his patient will receive perhaps a five-day dosage *until prior approval could be obtained.*" (Italics added.) (*Id.* at p. 108.) It is immediately apparent that the most critical shortcoming of the prior approval system in *Dodson* does not exist

in Medi-Cal plan. Both treatment and drugs may be provided in emergencies. Further, if communication with a Medi-Cal consultant could not be established and the service should not have been delayed, the Medi-Cal provider may get retroactive authorization for up to ten days after the service was provided or initiated. (Cal. Admin. Code, tit. 22, § 51003, subd. (b)(3).) In this respect, *Dodson* is simply not apposite to the present case.[15]

Nor do we find persuasive the particular holding in Jeneski v. Myers (1984) 163 Cal.App.3d 18 that the use of a doctor of pharmacy to render decisions on the issuance of TARs as to drugs invalidates the prior authorization procedure. This holding was based on the assertion these drug decisions must be made only by " 'one who is skilled in the medical field and perhaps even in certain specialities.' " (163 Cal.App.3d at p. 32.) No evidence to support this view was cited by the *Jeneski* court and the evidence that was recited in the opinion was from Medi-Cal recipients, doctors and pharmacists on the hazards of removing from the Medi-Cal formulary antihistamines, topical dermatological preparations, cold preparations and certain prescription drugs. In our view, the task of approving or tentatively denying a drug TAR is most competently performed by one trained and skilled in the "practice of preparing, perserving, compounding, and dispensing drugs", a pharmacist (see pharmacy, Webster's Ninth New Collegiate Dict. (1984) p. 881).

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[15] Similarly inapposite is California Medical Assn. v. Brian (1973) 30 Cal.App.3d 637. That case involved Medi-Cal regulations which were subsequently repealed. (*Id.*, at p. 649.) Acknowledging that the case was technically moot, this court went on to hold that the *procedures* by which the regulations were enacted violated both the Administrative Procedure Act and the Medi-Cal Act. (*Id.*, at p. 655.) In the present case plaintiffs do not contest that the statutes and regulations under consideration were properly enacted.

We note parenthetically that even lacking emergency procedures the plan in *Dodson* was not deemed *per se* medically unsound. (Dodson v. Parham, supra, 427 F.Supp. at p. 108.) Contrariwise, the trial court in this case held, notwithstanding the noted emergency procedures, that the Medi-Cal prior approval plan was unreasonable in its face.

We do concur with *Jeneski v. Myers*, supra, that if the department intends to deny a TAR it must afford the Medi-Cal recipient the opportunity for a predenial hearing. (Jeneski v. Myers, supra.) "Medicaid recipients have a right to a hearing prior to any state action resulting in the suspension, reduction, dicontinuance, or termination of assistance." (Bracco v. Lackner (N.D. Cal. 1978) 462 F.Supp. 436, 452, citing 45 C.F.R. § 205.10(a)(5).) Inasmuch as this right was previously guaranteed under federal regulations with which Medi-Cal provisions must be consistent, that the Legislature did not make specific provisions for such hearings in enacting the prior approval plan at issue does not amount to an infirmity in the TAR scheme thus adopted.

We conclude the trial court erred in finding the TAR system of prior authorization violative of the Act. Prior authorization is a permissible utilization control device contemplated by the Act, approved by the responsible federal agency and upheld by this court in *Margulis v. Myers*, supra, 122 Cal.App.3d 335. Since the State may define which services are medically necessary, it is proper to enforce this definition prior to provision of the services in appropriate circumstances. The TAR system is consistent with federal law.

IV

In one respect we are constrained to affirm the judgment of the trial court, but not for the reasons cited in its statement of decision. The department is without power to enforce any regulation which defines a medical necessity as that which is "medically necessary to protect life or prevent significant disability." The operative definition of a medical necessity is presently set forth in section 14059.5 as "reasonable and necessary to protect life or prevent significant disability, or to alleviate severe pain" and section 14133.3 mandates application of this standard by the director of the department. As the regulations enjoined by the trial court still include the former definition of a medical necessity, those regulations are unenforceable. Practically, as the regulations are generally duplicative of the statutory authority the

department is not precluded from enforcement of the statutory standards set forth in the amended legislation, section 14059.5.

V

The plaintiffs' cross-appeal points out a deficiency in the writ of mandate issued by the trial court. The writ precluded the State from utilizing prior authorization as a method of enforcing the standard of medical necessity set out in Welfare and Institutions Code section 14133.3, but failed to enjoin the use of either postservice prepayment audits or postservice postpayment audits. (Welf. & Inst. Code, § 14133, subds. (b), (c).) Plaintiffs contend the trial court's statement of decision struck down these postservice utilization controls in addition to the prior authorization system. Plaintiffs' cross-appeal seeks relief from this omission to prevent the State from doing postservice what the writ commands it may not do by prior authorization.

The matter is rendered moot by our holding the State may enforce its definition of medical necessity through the prior authorization system. If the State may reject a particular service as medically unnecessary prior to its provision, it follows a fortiori that it may do so after the service has been provided. Moreover, the cross-appeal fails to recognize that the federal Medicaid regulations *require* that a state plan contain "a post-payment review process that—[¶] (b) [i]dentifies exceptions so that the agency can correct misutilization practices of recipients and providers." (42 C.F.R. § 456.23(b).) The Medi-Cal postservice utilization control audits are consistent with the Act.

DISPOSITION

The judgment is reversed and the writ of mandate vacated save and except as to that portion restraining enforcement of regulations implementing the Welfare and Institutions Code which sets the standard for approval of Medi-Cal services and provides billings as "medically necessary to protect life or prevent significant disability." Costs shall be recovered by the appellant State agencies.

(CERTIFIED FOR PUBLICATION.)

CARR , J.

I concur:

EVANS , Acting P.J.

I dissent because the majority opinion is premised upon an improper characterization of the issues and hence does not address the dispositive question of statutory interpretation, the answer to which dictates a contrary result. The consequence of this oversight will be visited upon the tens, perhaps hundreds, of thousands of persons who will be denied needed medical services because their illnesses are less than life threatening or are deemed less than significant or are accompanied by pain that is less than severe.

The majority's critical mistake is that, with respect to the question—who determines the scope of medical services required to be offered under the federal law?—the majority opinion sets up a false dichotomy between the Legislature and the *individual* physician. The correct answer is neither, for it is a judicial question. The determination of the scope of medical services which the state must offer, because it requires an interpretation of the governing federal law, is a question for the courts to resolve. The dispositive question is whether the California statute conflicts with the controlling federal statutes. The judicial responsibility to determine if there is a conflict cannot be evaded by reposing it elsewhere.

The interpretive issue, never addressed by the majority opinion, is: whether the language of the federal statute, which mandates that the state provide *at the minimum* the care and services listed in paragraphs (1) through (5) and (17) of United States Code section 1396d (a) of Title XIX (namely: "(1) inpatient hospital services", "(2)(A) outpatient hospital services", "(3) other laboratory and x-ray services", "(4)(A) skilled nursing facility services", "(5) physicians' services" and "(17) services furnished by a nurse-midwife"), can be squared with California's drastic restriction of these services to those which are "reasonable and necessary to protect life to prevent significant illness or significant disability, or to alleviate severe pain." These restrictions are accomplished by defining "medical necessity" so as to include them. (Welf. & Inst. Code, § 14059.5.)

As will be shown, the governing federal statute bars the imposition of these restrictions. The United States Supreme Court has noted that the failure of a state to provide necessary

medical services in the mandatory categories would raise serious statutory problems. (Beal v. Doe (1977) 432 U.S. 438, 444-445 [53 L.Ed 2d 464, 472.) In my view, such problems are fatal to the restrictions imposed by California.

The dispostive question is – what is the *federal* definition of "medical necessity"? – for that is what is binding upon the states and hence upon the Legislature and the physician alike. The short answer is that the federal statutes provide a definition in Title XVIII (42 U.S.C. § 1395y (a)(1)(A)), which has consistently been equated with "medical necessity" in the federal case law. It provides that a service is "medically necessary" if it is "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member . . . ." This controlling definition is facially at odds with the more restrictive California law, which, perforce, must give way.

The majority opinion avoids this conclusion by avoiding the question to which it is the answer. It engages the wrong question which begets the wrong answer. Because at the outset the majority opinion goes off the tracks, I begin the analysis of the governing law, necessarily, at the place of derailment, the beginning.

I.

This is an appeal by the state from a judgment granting a peremptory writ of mandate. The writ, inter alia, would command the Director of the Department of Health Services not to enforce or implement Welfare and Institutions Code sections 14133.3 and 14133, subdivision (a). The theory of the judgment is that these statutes conflict with controlling federal law. Section 14133.3 limits coverage of the Medi-Cal program to services that are "medically necesssary", as defined by statute. Section 14133, subdivision (a) provides for a system of prior authorization for Medi-Cal services; under the system certain non-emergency services require administrative approval in advance of rendition or payment is denied. I consider each aspect of the peremptory writ separately.

II

Medi-Cal is California's medical assistance program under the Medicaid Act, Title XIX of the Social Security Act of 1956. The program funds medical assistance benefits for eligible needy persons who are aged, blind, disabled, or in families with dependent children. Once a state opts for participation in such a federal grant-in-aid scheme, the substance of its participation is governed by federal law. (E.g., King v. Smith (1968) 392 U.S. 309, 333 [20 L.Ed.2d 1118, 1134]. fn. 34.) Thus, state legislative enactments or administrative regulations which conflict with federal statutes, or lawful federal regulations implementing them, are invalid and void. The question on this appeal is whether the California statutes, which would limit Medi-Cal to care and services "reasonable and necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain", conflict with federal law.

The trial court found such a provision conflicts with federal law, inter alia, because it denies medical assistance for care and services which are "medically necessary" contrary to the requirements of Title XIX. I disagree with the reasoning of the trial court insofar as it implies that the standard of "medical necessity" is to be determined by individual physicians, but not with the conclusion that the state's definition of medical necessity conflicts with Title XIX.

The purpose of the Medicaid program is set forth in 42 United States Code section 1396 as follows: "[To enable] each State, as far as practicable under the conditions in such State, to furnish (1) medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services, and (2) rehabilitation and other services to help such families and individuals attain or retain capability for independence or self-care. . . ." This statement of purpose was enacted in 1965 when the Social Security Act was amended in pertinent part to expand the Medicaid program. (Pub.L.No. 89-97 (July 30, 1965) 79 Stat. 286; see sen. rep., 1965 U.S. Code Cong. & Admin. News 1943.) The amendment required for the first time that states participating in the program provide medical

assistance for certain designated categories of medical care and services. (See sen. rep., U.S. Code Cong. & Admin. News at pp. 1950-1951.) Presently these mandatory categories are impatient hospital services, outpatient hospital services, other laboratory and X-ray services, skilled nursing home services, physician services, and services furnished by a nurse midwife. (42 U.S.C. § 1396a (a) (10).) The Senate Report, in a segment entitled "scope of medical assistance", refers to these services as minimum benefit requirements. (See sen. rep., U.S. Code Cong. & Admin. News at p. 1950-1951.)

The threshhold question is: is the state at liberty to fashion its own definition of medical necessity as a limitation on these minimum benefit requirements? The answer is no. The meaning of "medical necessity" is fixed by the federal Medicaid statute and the companion amendments made in 1965 to the Medicare Act. Title XVIII of the Social Security Act of 1956. As appears, California's challenged definition of medical necessity would result in constriction of benefits below the minimum benefit requirements of the federal statute and hence it must be stricken.

A.

I first briefly set out the background of the challenged statutes.

At the outset of California's medical assistance program under the 1965 amendments to Title XIX the federal mandatory categories and several optional categories of care and services were provided under the rubric of "[h]ealth care and related remedial or preventive services." (See former Welf. & Inst. Code, §§ 14005, 14006.5, 14053, Stats. 1965, 2d Ex. Sess., ch. 4.) The only apparent limitation of coverage was contained in former section 14059 which, in conjunction with former section 14052, limited most services to "diagnostic, preventive, corrective, and curative services and supplies essential thereto, provided by qualified medical and related personnel for conditions that cause suffering, endanger life, result in illness or infirmity, interfere with capacity for normal activity including employment, or for conditions which may develop into some significant handicap . . . ." (Stats. 1965, 2d Ex. Sess., ch. 4.)

In 1975 this scheme was overlaid with a provision saying that benefits are limited to listed federal mandatory and optional categories of care and services, most of which are qualified by the clause "subject to utilization controls." (See Welf. & Inst. Code, §§ 14131, 14132.) The utilization controls are set out in section 14133. In pertinent part they require prior authorization for some services and subsequent audits for all services with coverage contingent upon a determination that the service is medically necessary. No statutory definition of medical necessity was provided initially.

In 1982 section 14133.3 was enacted saying that requests for prior authorization must be supported by documentation that "the requested services are medically necessary to protect life or prevent significant disability . . . ." The statute also directed that utilization controls be developed for all care and services implementing the same limitation. This enactment gave rise to this litigation.

In 1985 section 14059.5 was enacted and section 14133.3 was amended. Section 14059.5 says: "A service is 'medically necessary' or a 'medical necessity' when it is reasonable and necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain." As amended, section 14133.3 substituted the section 14059.5 standard of medical necessity for the prior formulation "necessary to protect life, or prevent significant disability . . . ." At issue is the present statute, since the order under review is injunctive in nature. Hence, it is necessary to address plaintiffs' present claim that sections 14059.5 and 14133.3 conflict with federal law.

The problem of the constraint of medical necessity and the flexibility accorded states to limit the scope of Medicaid benefits is not novel.[1] The only controlling authority addressing the topic is

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[1] One line of case law implicitly or explicitly assumes that all medically necessary services must be provided. (See e.g. Pinneke v. Preisser (8th Cir. 1980) 623 F.2d 546, 548, fn. 2, medical necessity is the standard for mandatory coverage.) Another line of case law assumes that the state is free to impose limitations on coverage which are premised on the perceived degree of medical necessity. (E.g. Curtis v.

Beal v. Doe, supra, 432 U.S. 438 [53 L.Ed.2d 464]. In *Beal*, Pennsylvania had promulgated a regulations limiting Medicaid coverage of abortion to cases where the procedure was certified by a physician to be medically necessary. (Id., at p. 441 [53 L.Ed.2d at p. 470].) The issue tendered was whether the regulation conflicted with the federal Medicaid statute in denying coverage for certain abortions; specifically, in denying coverage where there was no physician's certification that continuance of the pregnancy might threaten the health of the mother (in any manner other than the generic threat that inhers in termination of pregnancy by childbirth). (Id., at pp. 441, 445 [53 L.Ed.2d at pp. 470, 472].) The holding in *Beal* is that such a regulation is not invalid. (Id., at p. 447 [53 L.Ed.2d at p. 474].)

The *Beal* opinion acknowledges the requirement that states provide financial assistance for the care and services listed as mandatory in Title XIX. (Id., 432 U.S. at p. 444 [53 L.Ed.2d at p. 471].) "Although serious statutory questions might be presented if a state Medicaid plan excluded necessary medical treatment from its coverage, it is hardly inconsistent with the objectives of the Act for a State to refuse to fund *unnecessary*—though perhaps desirable—medical services." (Id., at pp. 444-445 [53 L.Ed.2d at p. 472].) The *Beal* court found that

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Taylor (5th Cir. 1980) 625 F.2d 645, 652.) In both lines the reasoning about the statutory meaning of the medical necessity is contaminated and confused by extraneous threads such as the role of the physician in the adjudicative question of existence of medical necessity and "discrimination" against particular illnesses prohibited under federal regulations. The closest case to this is Medical Soc. of State of N.Y. v. TOIA (2d Cir. 1977) 560 F.2d 535, but that case unaccountably treats the statutory reading question as one of fact and remands for trial. The law reviews are of some help but more for marshalling authority than resolution of the problem. (See Gosfield, Medical Necessity In Medicare and Medicaid: The Implications of Professional Standards Review Organizations (1978) 51 Temple Law Quarterly 229; Note, State Restrictions on Medicaid Coverage of Medically Necessary Services (1978) 78 Cal.L.Rev. 1491.) Since neither the case law nor secondary authorities provide an appropriate analytic base I merely note them here as an aside.

termination of pregnancy by abortion, absent an unusual threat to the health of the mother, is not medically necessary.

What is the nature of the serious federal statutory questions presented if a state excludes necessary medical treatment from Medicaid coverage? The obvious problem is that the exclusion of necessary medical treatment would conflict with the *minimum* benefit requirements of Title XIX. States may deny coverage within the mandatory categories if the care and services are not medically necessary. If states are also free to define medical necessity based upon the degree of urgency and their fiscal inclinations, the minimum benefit requirement provision is rendered a nullity.

Strictly speaking, necessity is an either/or concept. "A little bit necessary", like "a little bit pregnant", is an oxymoron. Implicit in the *Beal* opinion and in the federal statutory concept of medical necessity is that medical procedures are either medically necessary or not medically necessary. As appears, the meaning of the federal statutory concept "medically necessary" is fixed. Hence a state cannot redefine medical necessity according to its views of urgency of the need for medical assistance if the result is to deny mandatory coverage of procedures which are medically necessary within the meaning of the federal act.

The concept of medical necessity appears in various places in Title XIX. As related, the declaration of purpose defines eligibility in part on inability "to meet the costs of necessary medical services . . . ." (42 U.S.C. § 1396.) A later reference to this provision bears directly on the flexibility accorded to participating states to shape the content of their Medicaid programs. A state plan must "include reasonable standards . . . for determining . . . the extent of medical assistance under the plan which (A) are consistent with the objectives of [Title XIX] . . . ." (42 U.S.C. § 1396a (a) (17).) Hence, a state standard which denies coverage for "necessary medical services" within the mandatory service categories is not within the broad discretion conferred on states. (C.f. Pinneke v. Preisser, supra, 623 F.2d at p. 548; also *Beal*, supra, 432 U.S. at p. 444 [53 L.Ed.2d at p. 472].)

The concept of medical necessity also appears in Title XIX in provisions which advert to the utilization review provisions of Title XVIII. (See 42 U.S.C. §§ 1396a (30) and 1396 (i)(4) incorporating by reference the term "medical necessity" in 42 U.S.C. § 1395x (k).) This explicit nexus shows that the content of the concept of medical necessity is identical under both Titles. (See generally, Gosfield, Medical Necessity, supra, 51 Temple L.Q. at pp. 238-243.) That conclusion is reinforced by the enactment of both Titles in their modern guise in the same bill in the Social Security Act amendments of 1965. This implication in turn is strengthened by the legislative history indicating that the two Titles are part of a "coordinated approach." (See Roe v. Norton (2nd Cir. 1975) 522 F.2d 928, 940, conc. and dis. opn. of Mulligan, J.)

There is no express definition of the term "medical necessity" in Title XIX. However, that does not mean that there is no statutory content to the term. (See Pinneke v. Preisser, supra, 623 F.2d at p. 548.) There is a candidate for a statutory definition of medical necessity in Title XVIII. Under this Title coverage is ordinarily denied unless the medical procedure is "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. . . ." (42 U.S.C. § 1395y (a)(1)(A).) This provision has been consistently equated with the term medical necessity in federal medicare case law. (See e.g. Hultzman v. Weinberger (3d Cir. 1974) 495 F.2d 1276, 1282; Mount Sinai Hosp. of Gr. Miami, Inc. v. Weinberger (5th Cir. 1975) 517 F.2d 329, 335.) As I have shown, the Title XIX provisions advert to the utilization review provisions of Title XVIII so as to equate the meaning of "medical necessity" under both titles.

Beal, supra, implies that the content of the term medical necessity is determinate and determinable as a matter of federal law. Indeed, the fundamental precept of law, consistency, impels the conclusion that medical necessity cannot have a different meaning in different states. The *Beal* opinion suggests that medical necessity is a medical judgment that the measure is reasonable to safeguard or improve the health of the patient. (See *Beal*, supra, 432 U.S. at p. 441 [53 L.Ed.2d at p. 470], fn. 3.) This is

entirely consistent with employment of 42 United States Code section 1395y (a)(1)(A) as the federal definition of medical necessity. Moreover, this definition accounts for the holding in *Beal* that "non-therapeutic" abortion is not required to be covered by a state Medicaid plan. A normal pregnancy is not in ordinary usage called an injury or illness nor does a "non-therapeutic" abortion improve the functioning of a malformed body member. (Cf. Geduldig v. Aiello (1974) 417 U.S. 484, 496 [41 L.Ed.2d 256, 264-265. fn. 20].)

Use of this definition also comports with the usage of "medically necessary" I would expect in ordinary speech. One would say a care or service was medically necessary if undertaken pursuant to a physician's professional advice to prevent, cure, or alleviate illness, injury, or malformation of a body member.

Any narrower definition of medical necessity would have to be premised on the perception that the phrase is a technical term. But there is no textual or contextual indication that any special or technical meaning is appropriate. Moreover, any such construction would rebuff the canon that remedial legislation such as the Medicaid Act should be construed liberally. (See e.g., Brooks v. Smith (Me 1976) 356 A.2d 723, 729.) Under this canon an ambiguous term is ordinarily construed in favor of coverage for the recipient. (See e.g. In-Home Supportive Services v. Workers' Comp. Appeals Bd. (1984) 152 Cal.App.3d 720, 733.)

California's proferred definition of medical necessity challenged in this case is medical services "reasonable and necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain." Under Welfare and Institutions Code sections 14059.5 and 14133.3, this definition is injected into the system of utilization controls and is applied to all services, including those services made mandatory by Title XIX. This definition is in facial conflict with federal law insofar as it would deny coverage for "medically necessary" care and services (as defined under federal law) for mandatory categories of care and service under the Medicaid Act. Medical care and services reasonably recommended to diagnose, cure, or prevent minor illness, to improve the functioning of a malformed body member regardless if it amounts to a significant disability, or to alleviate

moderate pain or minor discomfort which attend injury or illness must be provided within mandatory service categories. Hence, language in California's statutes which would exclude coverage of such care and services is invalid on the ground of federal supremacy.

B.

I am not swayed from this conclusion by the consideration that the Department of Health and Human Services advocates the contrary position. The question is one of interpretation of the federal statute.[2] As to such questions the view of the responsible administrative agency is not binding upon the court. (See e.g. Batterton v. Francis (1977) 432 U.S. 416, 425 [53 L.Ed.2d 448, 456], fn. 9; 2 Davis, Administrative Law Treatise (2d ed. 1979) § 7:13.) The degree of weight accorded the agency view varies based upon the confidence of the court in its own reading of the statute, the pertinence of expertise of the agency to the matter at hand, and various technical considerations such as whether the agency view is a contemporaneous construction, of long duration, has been consistently maintained, or if embedded in a regulation,

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[2] The Secretary of Health and Human Services is given general authority to promulgate rules and regulations regarding Medicaid that are "not inconsistent" with the statute and necessary to the efficient administration of the functions with which he is charged under the statute. (42 U.S.C. § 13Q2.) As to certain matters the secretary is given substantive authority to prescribe standards, e.g. standards for income and resources to be considered available to recipients under 42 United States Code section 1396a (a)(17)(B). There is no indication in the statute that the secretary has been assigned substantive authority to prescribe standards regarding the content of minimum benefit requirements of the mandatory categories of care and services under section 1396a (a)(10). Hence, even if the secretary had promulgated a regulation purporting to govern such matters and inconsistent with my reading of the statute, the regulation would be subject to review as an administrative interpretation. It would not be accorded the special deference accorded administrative rules promulgated under a grant of delegated legislative authority. (See 2 Davis, Administrative Law Treatise, supra, §§ 7.8, 7.13.)

has been impliedly endorsed by statutory re-enactment. (See Ibid.)

Here, the opposition of the Department of Health and Human Services is an insufficient consideration to dissuade me from my announced reading of the Medicaid statute. Although the statutory question requires a complicated analysis I have a high degree of confidence that the analysis is correct. The department offers no legal argument which shakes that confidence into the realm of significant doubt. The department presents no reasoned explanation of the manner in which esoteric questions within its special administrative expertise may be clouding my view. Nor is there any indication that any of the potential technical considerations mentioned above strongly commend deference to the department's view in this case.

C.

The language in sections 14095.5 and 14133.3 which would produce the unlawful effect in conflict of federal law is invalid and must be stricken. (See People's Advocate, Inc. v. Superior Court (1986) 181 Cal.App.3d 316, 330-334.) But this language is the core and only substance of these challenged statutes. The provisions should be stricken in their entirety on the ground that no mechanical severence of invalid language is possible. A court is not at liberty to rewrite the provisions, e.g. by inserting qualifications limiting their applications to non-mandatory services under Title XIX. (Id., at p. 330, fn. 15.) Hence, it is not necessary to consider the other arguments concerning validity and invalidity of sections 14095.5 and 14133.3 tendered by the parties.

III

The second main component of the writ would extinguish the prior authorization scheme under seciton 14133. As best I can determine from the statement of decision, the trial court concluded that this scheme conflicts with Title XIX on various grounds. The statement of decision suggests that section 14133 unlawfully limits coverage of services that are medically necessary, that section 14133 conflicts with an implicit federal mandate

that physicians decide whether a care or service is medically necessary, that because of fiscal constraints the prior authorization system operates with less staff than reasonably required to process requests for prior authorization, that the prior authorization system costs more than it saves, and that many drugs which are medically necessary are, to a substantial degree, unobtainable under the prior authorization system.

The first question is: What is the effect of the conclusions concerning the invalidity of sections 14133.3 and 14059.5 on the rationale that section 14133 unlawfully limits Medi-Cal coverage of care services that are medically necessary? As related, section 14133 was enacted without an explicit statutory definition of the term "medical necessity." Section 14133.3 and later section 14059.5 were subsequently enacted defining medical necessity implicitly initially and explicitly thereafter. These subsequent enactments were viewed as cost saving measures. Such savings could only have stemmed from a contraction of the coverage under Medi-Cal, i.e., from a constriction of the term "medical necessity." Hence, section 14133.3 and later section 14059.5 must be viewed as implied amendments of section 14133. As such, when the amendments are stricken, the meaning of medical necessity in section 14133 is returned to its original unconstricted usage. "Generally stated, the rule is that when discrimination or unconstitutionality results from a statutory amendment, as is the case here, it is the amendment which is invalid and not the origianl portions of the statute." (Miller v. Union Bank & Trust Co. (1936) 7 Cal.2d 31, 36.)

With the unlawful gloss of sections 14133.3 and 14059.5 removed, I would construe the meaning of "medical necessity" in section 14133 as identical with the previously discussed definition of that term under the federal law of Title XIX. Having so construed section 14133 I discern no conflict between it and the federal law mandate concerning minimal requirements for services under the Medicaid Act. Hence, none of my reasoning concerning invalidity of sections 14133.3 and 14059.5 supports a finding of invalidity of section 14133. To the extent that the component of the proposed writ addressed to section 14133, subdivision (a) is based upon that rationale, it is unwarranted.

The trial court's concern about unavailability of medically necessary drugs is also extinguished by the invalidation of sections 14133.3 and 14059.5.

These conclusions call into question the entire judgment insofar as it extends to matters beyond the invalidity of section 14133.3 and section 14059.5. The nature of the statement of decision is such that I cannot disentangle the findings of the trial court and determine whether any of the other restraints of the proposed writ would have been imposed upon the state if the "medical necessity" problem had been correctly analyzed and confined. As to the restraint on the enforcement or implementation of section 14133, none of the other reasons given in the statement of decision tenders a challenge to that statute's validity on its face. At most these reasons pertain to possible conflict with federal law in the manner in which the statute has been applied, i.e., in the administrative scheme established under the statute.

The appropriate resolution is to overturn the remainder of the judgment and return the matter to the trial court for reconsideration in view of this reasoning. That I would do. That tenders several other concerns.

IV

A principal concern of the trial court was the perceived mandate of Title XIX that the individual physician determine the medical necessity of services provided to Medi-Cal recipients. The trial court's perception of the scope of this mandate may be somewhat overblown. I find no intimation in the federal law that the judgments of individual physicians concerning the medical necessity of services are not subject to review. Regardless of the hope that the practice of the art of medicine not be unduly hindered by heavy-handed bureaucratic second-guessing, the federal law expressly mandates utilization controls which encompass review to safeguard against unnecessary utilization of services. (42 U.S.C. § 1396a (a)(30).) Moreover, as to care and services within the optional categories of Title XIX, it is not immediately apparent why a state whould not be able (by lawful means) to limit its degree of participation to coverage of circumstances more

grave than all those encompassed by the federal medical necessity standard.

As to care and services that a state has lawfully declined to cover there is nothing inherently improper in denying reimbursement via an administrative prior authorization scheme. Even as to those categories of care and services where medical necessity is a federal criterion of mandatory coverage, there is no intrinsic impropriety in such screening. Ultimately, questions of medical necessity are questions of public law and adjudicative fact. The deference granted to the physician pertains to expertise on the adjudicative fact component. But even that deference is not to the idiosyncratic opinion of individual physician, rather it is to the professional judgment of that physician, subject to and contrained by professional norms of justification and the underlying standard of public law.

As to the claim that the administrative costs of such a scheme outweigh the actual savings in lawful denial of non-covered care and services, I am unpersuaded. The argument is certainly not novel. (See tenBroek, California's New Medical Care Law and Program (1958) 46 Cal.L.Rev. 558, 579-583.) Here the evidence of costs and benefits is very sketchy and does not account for possible savings in deterrence of inappropriate utilization of care and services. Moreover, this is the sort of argument that should be addressed to the lawmaker. (See American Bank & Trust Co. v. Community Hospital (1984) 36 Cal.3d 359, 372-374.)

V

This is not to say, however, that a prior authorization scheme may not in practice run afoul of federal law. The state cannot employ a prior authorization scheme which has the purpose or effect of non-compliance with federal substantive mandates. If, as a practical matter, an administrative prior authorization scheme unreasonably results in denial of covered care and services to eligible recipients that scheme is in conflict with federal law. For example, a state could not require prior authorization if it refused to provide adequate personnel to allow the scheme to function in a manner consistent with timely provision of such care and services.

If the inadequate quantity or quality of staff for a prior authorization scheme resulted in unreasonable delays or an unreasonably high level of incorrect denial of authorization this could present a violation of federal law. To choose an extreme example, authorization for care and services could be regularly delayed until illnesses for which they are medically necessary had run their course. This would raise a substantial question of compliance with federal mandates. (See e.g., 42 U.S.C. § 1396a (a)(10) discussed, supra, section I *ante*; 42 U.S.C. § 1396a (a)(19) [a state plan must assure that covered care and services will be provided, in a manner consistent with simplicity of administration and the best interests of recipients]; 42 U.S.C. § 1396(a)(30) [utilization review procedures must be consistent with efficiency, economy, and quality of care].)

Here the original statement of decision contains evidence that may raise serious federal questions. The state admitted that "Because of fiscal shortages, [the state is] forced to operate with less than the full complement of staff reasonably required to process [requests for prior authorization]." The offices which can grant prior authorization are closed weekends, holidays, and evenings. Processing of prior authorization by mail often takes as long as 9 to 13 days. There was evidence that obtaining prior authorization approval by telephone can be a protracted, frustrating ordeal. It is difficult to obtain an open line to prior authorization offices, the transcribers who take incoming calls are unfamiliar with medical terminology, and delay in the process leads to detriment to patients' health.

I imply no view on the question is there sufficient evidence to condemn the state's administrative scheme purporting to implement section 14133. In any event, such a finding would not warrant a writ commanding that no implementation or enforcement of section 14133 occur. At most the relief warranted would be a command to cease requiring prior authorization until the defects which raised substantial federal compliance questions were cured. As related, I cannot discern what the unalloyed findings of the trial court would have been regarding such compliance questions. Moreover, changes in the situation as a result of an invalidation of sections 14133.3 and 14059.5 and changes

attributable to the passage of time and the possible effects of other unknown developments would render it unwise to attempt to reform the judgment at the appellate level as pertains to aspects beyond the invalidation of those statutes.

I would affirm the judgment insofar as it orders issuance of a peremptory writ commanding the state not to implement or enforce Welfare and Institutions Code section 14133.5 and would modify it to include Welfare and Institutions Code section 14059.5 within this proscription and as so modified affirm it. In all other respects I would reverse the judgment for further proceedings.

BLEASE, J.

Appendix B

In the Court of Appeal of the State of California

in and for the

Third Appellate District

3 Civil 22987

Sacramento 308404

Stephen Cowan, et al.

v.

Beverlee A. Meyers, et al.

By the Court:

Respondents' petition for rehearing is denied.

Dated: January 7, 1987.

Evans, Acting P. J.

Appendix C

Order Denying Review

After Judgment by the Court of Appeal

3rd District, Civil No. 22987

In the Supreme Court of the State of California

In Bank

Cowan et al.

vs.

Myers etc., et al.

[Filed April 2, 1987]

Appellants' petition for review DENIED.

Mosk, J., Broussard, J. and Kaufman, J., are of the opinion the petition should be granted.

Lucas
Chief Justice

Appendix D

Superior Court of the State of California
County of Sacramento
No. 308404

Stephen Cowan, Chester Dupont, Lorna Purkey
and Frederick S. Mayer,
Petitioners,

vs.

Beverlee A. Meyers, Acting Director,
Department of Health Services,
State of California;
Peter Rank, successor Director,
Department of Health Services
State of California;
Department of Health Services,
State of California;
Kenneth Cory, Controller, State of California;
and Jesse Unruh, Treasurer,
State of California,
Respondents.

JUDGMENT

[Filed May 31, 1983]

The trial of the above-entitled proceeding having come regularly before me on February 7 through 9, 1983, the parties appearing by and through their respective counsel, Lynn S. Carman for petitioners, and John K. Van De Kamp, Attorney General, by John W. Spittler, Deputy Attorney General, and good cause appearing,

IT IS HEREBY ORDERED, ADJUDGED AND DECREED that petitioners have judgment in their favor, and against respondents, and each of them, together with costs as provided by law;

IT IS FURTHER ORDERED, ADJUDGED AND DECREED that the words and figures of the Statement of Decision, signed and filed herewith, are incorporated in this judgment and made a part hereof;

IT IS FURTHER ORDERED, ADJUDGED AND DECREED that the Clerk of this Court shall forthwith issue a writ of mandamus, in the words and figures in Exhibit 1 annexed hereto.

IT IS FURTHER ORDERED, ADJUDGED AND DECREED that the Court retains continuing jurisdiction to issue all necessary further orders to carry out, implement and effect this judgment.

IT IS FURTHER ORDERED, ADJUDGED AND DECREED that this judgment, including the issuance of the writ of mandamus, shall be, and is hereby stayed, and be of no force or effect, for 20 days following the filing of this judgment, in order to allow respondents time within which to apply for or receive a stay from an appellate court.

Dated: May 31, 1983.

/s/ WILLIAM A. WHITE
Judge

Exhibit 1

Superior Court of the State of California

County of Sacramento

No. 308 404

Stephen Cowan, Chester Dupont, Lorna Purkey,
and Frederick S. Mayer,
Petitioners,

vs.

Beverlee A. Meyers, Acting Director,
Department of Health Services, State of California;
Peter Rank, successor Director, Department of Health Services,
State of California;
Department of Health Services, State of California;
Kenneth Cory, Controller, State of California; and
Jesse Unruh, Treasurer, State of California,
Respondents.

Peremptory Writ of Mandamus

THE PEOPLE OF THE STATE OF CALIFORNIA to each and all of the above-named respondents, and their employees and agents, Greetings:

WE DO COMMAND YOU, and each of you, and your employees and agents, forthwith upon receipt of this writ, to permanently refrain:

(1) From enforcing or emplementing, directly or indirectly, § 14133.3 Welfare & Institutions Code, ("W&I Code"), in whole or in part, or any regulation, formal or informal, implementing § 14133.3 W&I Code, directly or indirectly; or from requiring that any physicians' services, drugs or services or benefits be "medically necessary to protect life or prevent significant disability", or from using such standard in approving Medi-Cal services and provider billings;

(2) From enforcing or implementing, directly or indirectly, § 14133(a) W&I Code, in whole or in part, or any regulation,

formal or informal, implementing § 14133(a) W&I Code, directly or indirectly;

(3) From requiring prior authorization (to wit, approval by the Director of Health Services, State of California, or by the Department of Health Services, State of California, or their employee, of a specified service or services based upon a determination of "medical necessity"), in respect to any Medi-Cal service or benefit;

(4) From disapproving, denying, withholding, reducing or recouping payment to any Medi-Cal provider or eligible recipient, upon the claim, basis or ground:

(a) that the particular physicians' service, prescribed drug or other prescribed benefit or services was not "medically necessary to protect life or prevent significant disability";

(b) the prescribed drug is not on the Medi-Cal Drug Formulary, or

(c) the prescribed drug is available "over-the-counter" without prescription, or

(d) that the outpatient psychiatric service exceeded 8 visits or some specified number of visits in a 120-day period or other specified period, or

(e) that the elimination of "prior authorization" by this judgment and peremptory writ of mandamus eliminated the Medi-Cal coverage for that particular benefit or service;

(5) From enforcing or implementing, directly or indirectly, the provisions, in whole or in part, of the following paragraphs set forth in the Letter attached, (Exhibit A, whose words and figures are incorporated herein):

New Definition of Medical Necessity
Hearing Aid Batteries
Drugs and Medical Supplies
Nonemergency Medical Transportation
Psychiatry
Other Services;

(6) From denying restorative breast surgery to pertitioner Lorna Purkey, including all physicians' services, prescribed drugs, hospital in-patient and out-patient, and other necessary Medi-Cal benefits attendant thereto, including but not limited to follow-up physicians' services, prescribed drugs, and other Medi-Cal benefits related to and flowing from such restorative breast surgery;

(7) From denying the drug Sudafed to Stephen Cowan, when prescribed by his physician, or any other covered Medi-Cal service prescribed for him by his physician as being "medically necessary";

(8) From denying any Medi-Cal benefits to Lorna Purkey, in respect to Paragraph 6 hereinabove, on the claim, basis or ground that her AFDC eligibility has terminated, or that she does not have a valid or any Medi-Cal indentification card or sticker any longer; (a certified copy of this writ of Peremptory Mandamus shall be authority to any provider and to the Department of Health Services to furnish the services under Medi-Cal described in Paragraph 6).

WITNESS the Honorable WILLIAM A. WHITE, Judge of the Superior Court in and for the County of Sacramento, State of California.

ATTEST MY HAND AND THE SEAL OF THIS COURT this day of , 1983.

CLERK

By

Deputy Clerk

(SEAL)

Department of Health Services

Exhibit A

Important Changes in Medi-Cal Benefits

Effective September 1, 1982, there will be certain reductions in Medi-Cal services. These changes are necessary to comply with changes in state law.

New Definition of Medical Necessity

Coverage of medical, surgical, and other services will be limited to only those services which are considered medically necessary to protect life or prevent significant disability. Those elective services which can be eliminated without seriously endangering your life or causing you a significant disability will no longer be approved. The final determination of the medical necessity of any given medical service will be made by a Medi-Cal medical consultant in your area in conjunction with your doctor, podiatrist, or other provider of service in accordance with the above guidelines. If you are denied a service and your condition worsens to the point where further denial would endanger your life or cause significant disability, the service can be reconsidered for approval.

Eyeglasses

Medi-Cal coverage of new and replacement eyeglasses will be limited to those which correct a significant visual impairment. Additionally, trifocal eyeglasses will no longer be covered and, with the exception of eyeglasses for persons who have had a cataract operation, coverage of tinted eyeglasses will end.

Eye Examinations

Routine eye examinations for persons age 21 and older who have not had a cataract operation will be limited to a screening examination once every 2 years. If a vision problem arises within two years of an eye examination, a screening examination can be provided. A complete eye examination can be provided when the screening examination discloses the presence of a medical condition requiring a comprehensive evaluation. Present coverage of

eye examinations will not change for persons under age 21 and persons who have had a cataract operation.

Hearing Aid Batteries

Replacement hearing aid batteries will not be covered. However, the initial batteries supplied with a new hearing aid will continue to be covered.

Drugs and Medical Supplies

There are also reductions in the coverage of certain drugs and medical supplies. Cotton, adhesive tapes, and elastic bandages will not be covered. Drug program reductions will include the elimination of antihistamines, cough and cold preparations, antipruritics, quinine, codeine-containing compounds used for minor pain relief, and other minor pain relievers except for aspirin, acetaminophen, and sodium salicylate. A number of drugs will be covered only after prior authorization including dermatological preparations, sedatives and hypnotics (sleeping pills), and certain anti-inflammatories (except for aspirin) used for arthritis and similar conditions. Your pharmacist and doctor will receive details in mid-August on the changes in coverage of specific drugs.

Nonemergency Medical Transportation

Nonemergency medical transportation will no longer be available from your place of residence to any other medical care unless travel by car or bus is medically dangerous and you require dialysis, chemotherapy, radiation therapy, or treatment for a comparably life-threatening condition. Nonemergency medical transportation will still be available under most circumstances for patients in hospitals or nursing homes. Medi-Cal recipients are responsible for using whatever means they have, including family and friends, in order to get to and from health care. If you have exhausted such private resources and cannot postpone your health care, you may wish to contact the local county welfare department for information and referral to other community sources of transportation.

Department of Health Services

Exhibit A

Important Changes in Medi-Cal Benefits

Effective September 1, 1982, there will be certain reductions in Medi-Cal services. These changes are necessary to comply with changes in state law.

New Definition of Medical Necessity

Coverage of medical, surgical, and other services will be limited to only those services which are considered medically necessary to protect life or prevent significant disability. Those elective services which can be eliminated without seriously endangering your life or causing you a significant disability will no longer be approved. The final determination of the medical necessity of any given medical service will be made by a Medi-Cal medical consultant in your area in conjunction with your doctor, podiatrist, or other provider of service in accordance with the above guidelines. If you are denied a service and your condition worsens to the point where further denial would endanger your life or cause significant disability, the service can be reconsidered for approval.

Eyeglasses

Medi-Cal coverage of new and replacement eyeglasses will be limited to those which correct a significant visual impairment. Additionally, trifocal eyeglasses will no longer be covered and, with the exception of eyeglasses for persons who have had a cataract operation, coverage of tinted eyeglasses will end.

Eye Examinations

Routine eye examinations for persons age 21 and older who have not had a cataract operation will be limited to a screening examination once every 2 years. If a vision problem arises within two years of an eye examination, a screening examination can be provided. A complete eye examination can be provided when the screening examination discloses the presence of a medical condition requiring a comprehensive evaluation. Present coverage of

eye examinations will not change for persons under age 21 and persons who have had a cataract operation.

Hearing Aid Batteries

Replacement hearing aid batteries will not be covered. However, the initial batteries supplied with a new hearing aid will continue to be covered.

Drugs and Medical Supplies

There are also reductions in the coverage of certain drugs and medical supplies. Cotton, adhesive tapes, and elastic bandages will not be covered. Drug program reductions will include the elimination of antihistamines, cough and cold preparations, antipruritics, quinine, codeine-containing compounds used for minor pain relief, and other minor pain relievers except for aspirin, acetaminophen, and sodium salicylate. A number of drugs will be covered only after prior authorization including dermatological preparations, sedatives and hypnotics (sleeping pills), and certain anti-inflammatories (except for aspirin) used for arthritis and similar conditions. Your pharmacist and doctor will receive details in mid-August on the changes in coverage of specific drugs.

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Psychiatry

Outpatient psychiatry services will be limited to 8 visits in any 120-day period. Additional visits will no longer be available through prior authorization.

Other Services

Physical therapy, podiatry, portable X-ray services, certain outpatient medical and surgical procedures, and outpatient heroin detoxification services will not be covered unless prior authorization is obtained from the Medi-Cal field office medical consultant. Your doctor or other provider will be informed of the procedure to follow in obtaining prior authorization. Your *MEDI* sticker can no longer be used for physical therapy or podiatry.

Right to Appeal

If you are denied a Medi-Cal service, you may have the right to appeal the denial. If you decide to request a state hearing, you must do so within 90 days of the date of the denial. You may request a hearing by contacting:

Office of the Chief Referee
State Department of Social Services
744 P Street, Mail Station 6-100
Sacramento, CA 95814

If you have any questions about these changes, you may call the Department of Health Services, Medi-Cal Relations Unit, at (916) 445-0266.

Appendix E

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Attorneys for Petitioners

Superior Court of the State of California

County of Sacramento

No. 308 404

Stephen Cowan, Chester Dupont,
Lorna Purkey, and Frederick S. Mayer,

Petitioners,

vs.

Beverlee A. Meyers, Acting Director,
Department of Health Services, State of California;
Pete Rank, successor Director, Department of Health
Services, State of California; Department of Health
Services, State of California; Kenneth Cory, Controller,
State of California; and Jesse Unruh, Treasurer, State
of California,

Respondents.

Statement of Decision
[Filed May 31, 1983]

PART I

1. The Medicaid Act, Title XIX of the Social Security Act of 1956, operates to enable participating states, through the use of federal funds, to provide medical services to welfare recipients (the "categorically needy"), and if the state chooses, to other needy recipients (the "medically needy"). Although a state's participation in Medicaid is voluntary, if it chooses to adopt a plan it must do so consonant with the requirements imposed by the

Medicaid Act. (*Preterm, Inc. v. Dukakis* (1st Cir 1979) 591 Fed.2d 121, 124).

2. The Medicaid Act now requires that six services be provided to needy eligible recipients, (inpatient hospital; outpatient hospital; laboratory and x-rays; skilled nursing facility; physicians; and nurse-midwife), (hereinafter called "Required Services"); and authorizes federal funding of 16 other services, including prescribed drugs, ("Optional Services"). (42 U.S.C. §§ 1396a(a)(10)(A) and 1396d(a)(1)-(17)).

3. California has accepted Medicaid federal funding and has enacted a Medicaid program, called Medi-Cal, § 14000 et seq. Welfare & Institutional Code. (All references are to the Welfare & Institutions Code, unless otherwise specified.). Medi-Cal provides the six Required Services, and most if not all of the Optional Services, including prescribed drugs. (§§ 14132 and 14132.4). All the services are, by statute, subject to "utilization controls". (§§ 14132, 14132.4).

4. Prior to Assembly Bill 799 enacted in 1982, the standard of Medi-Cal for furnishing Medicaid benefits was that of "medical necessity". (§ 14133 and 22 Cal.Adm.Code § 51502(d), requiring "medical necessity" for payment and for prior approval.)

5. In 1982 the Legislature enacted § 14133.3.[1] Section 14133.3 fundamentally changed the standard for furnishing Medi-Cal benefits to that "medically necessary to protect life or prevent significant disability."

6. The question raised is whether or not § 14133.3 violates the Medicaid Act. It does, for the following reasons:

7. The Medicaid Act requires that:

> "A state plan for medical assistance must— . . . include reasonable standards . . .". (42 U.S.C. § 1396a(a)(17).

In inserting the requirement of "reasonable standards" in the same statute which provided for Required Services and Optional

---

[1] Stats 1982 ch 328 § 38, eff. 6/30/82, amended Stats 1982 ch 1594 § 61, eff. 9/30/82.

Services, Congress plainly intended that Optional Services as well as Required Services must have "reasonable standards". The Supreme Court has held that the language of 42 U.S.C. § 1396a(a)(17) requires:

> ". . . that such standards be 'reasonable' and 'consistent with the objectives' of the Act." (*Beal v. Doe*, 432 U.S. 438, 444, 53 L.Ed.2d 464, 97 S.Ct. 2366, 2371).

The objective of the Medicaid Act is set forth in *Preterm, Inc. v. Dukakis* (1st Cir 1977) 591 Fed.2d 121, 126:

> "The Medicaid system was established for the purpose of enabling a state, with federal participation, to provide medical assistance to elgible individuals in need of treatment and unable to pay for it. See 42 U.S.C. § 1396."

Since that is the objective, a standard whereby an offered Medicaid service is available when medically necessary to the elgible needy, is reasonable and consistent with the objectives of the Act; whereas a State standard as in this case at bar, whereby an offered Medicaid service is not available in many instances of medical necessity, or is not available in a substantial range of medically necessary situations to the eligible needy, is unreasonable and wholly inconsistent with the objectives of the Act. This is true whether the service is a Required Service of merely an offered Optional Service, because, as noted prior, the "reasonable standards" requirement of 42 U.S.C. § 1396a(a)(17) applies to both. (A state may choose not to offer an Optional Service at all; but if it does, it must meet this "reasonable standards" requirement of 42 U.S.C. § 1396a(a)(17).)

8. Inasmuch as limitations on Medi-Cal beneifts in § 14133.3 restricts such benefits to only those Required Services and Optional Services, (including physicians' services, drugs and procedures), which are "medically necessary to protect life or prevent significant disability", § 14133.3 of the Medi-Cal Act is contrary to the federal Medicaid Act and therefore, illegal and void. Such limitations unduly curtail medical assistance to the elgible poor, by denying medically necessary services, contrary to the objectives of the Medicaid Act. (42 U.S.C. §§ 1396, 1396a(a)(17)).

9. Inasmuch as limitations on Medi-Cal benefits in § 14133.3 restricts such benefits to only those Required Services and Optional Services, (including physicians' services, drugs and procedures), which are "medically necessary to protect life or prevent significant disability," § 14133.3 is contrary to the federal Medicaid Act and, therefore, illegal and void. Such limitations unduly curtail medical assistance to the eligible poor, and are unreasonable and wholly inconsistent with the objectives of the Medicaid Act. (42 U.S.C. § 1396, § 1396a(a)(17)).

10. It is unreasonable and wholly contrary to and inconsistent with the objectives of the Medicaid Act, (42 U.S.C. § 1396, § 1396a(a)(17)), for a state to provide Required Services and Optional Services, respectively, and then deny them to all those who will not die or be significantly disabled therefrom; and therein, § 14133.3 is contrary to the Medicaid Act and, therefore, illegal and void. (see *Preterm, Inc. v. Dukakis*, 591 Fed.2d 121, 125.)

11. Moreover, § 14133.3 violates the federal mandate which requires, in respect to Required Services and offered Optional Services, that:

> "Each service must be sufficient in amount, duration and scope to reasonably achieve its purpose." (42 CFR § 440.230(b)).

This is also implicit in the Medicaid Act, as Congress could Therein, § 14133.3 is contrary to the Medicaid Act and, therefore, illegal and void in respect to Required Services.

Testimony concerning § 14133.3 standard and enforcement.

14. Jerome Lackner, M.D., J.D., Sacramento physician with a large Medi-Cal practice, and former director of Medi-Cal from 1975 to 1978 as the director of the then-Department of Health, testified, (RT 215, 222 and 224),—and the Court finds,—that (1) the § 14133.3 limitation denies a significant range of medical necessary procedures, treatment and drugs which are medically necessary, (2) a standard of treatment with the § 14133.3 limitation is insufficient in amount, duration and scope to achieve its purpose, and (3) the § 14133.3 limitation denies medical treat-

ment because of diagnosis, type of illness, and conditions. Dr. Lackner testified,—and the Court finds,—: that the Medi-Cal Drug Formulary is insufficient, giving very little consideration to pain, which is a major medical problem, (RT 217-219); that the § 14133.3 limitation results in non-treatment of disease at the entry stage which progresses into serious disease, (RT 216); that elimination of medically necessary nonsteriodal anti-inflammatory drugs, (NSAIDs) from the Drug Formulary has produced as increase in codeine-caused problems such that there are seven times more codeine prescribed to Medi-Cal recipients as to non-Medi-Cal patients, (with 8 times the per-capita basis of codeine use as well as all other states combined), (RT 219-220); that most of the procedures listed by Medi-Cal in its provider bulletins as being excluded from coverage, or as being subject to prior authorization under the § 14133.3 standard, are both generally accepted procedures and medically necessary in situations warranting their use, (RT 207-214); that many patients are unable to tolerate drugs on the Formulary, (RT 219); that the number of overdoses and disability secondary to toxicity in codeine is on a rapid rise in this state, due to Medi-Cal restrictions, (RT 220); it is extremely hard to treat gout with the drugs on the Formulary, (RT 222); that the § 14133.3 standard almost excludes the practice of dermatology on Medi-Cal patients, (RT 224); and that the effect of prior authorization with the § 14133.3 restriction increases hospitalizations, (RT 227).

15. Frederick S. Mayer, BPh., MA in public health, and president of the California Public Health Association and of Pharmacists Planning Services, Inc., (an organization of 220 pharmacists), testified,—and the Court finds,—that the denial of non-Formulary drugs by the § 14133.3 limitation denies patients basic pharmaceutical care and increases hospitalizations; causes patients denied the needed drug to go to emergency rooms where the care is more expensive; and causes physicians to prescribe counter-indicated Formulary drugs for lack of ability to obtain the drug of treatment choice and that the § 14133.3 restriction denies medically necessary drugs and prevents the prescribed drug program from being sufficient in amount, duration and scope to achieve its purpose. (RT 132-133).

16. Testimony of non-Department physicians and pharmacists at the November 19, 1982 drug hearing, corroborated the testimony of Dr. Lackner and pharmacist Mayer. (Exhibit 1, RT 27-152, in evidence by stipulation). Also, therein, Lee Strandberg, associate professor of pharmacy, Oregon State University, specialist in pharmacy administration, testified,—and the Court finds,—that deletion of medically necessary drugs from the Drug Formulary does not reduce the cost of health services.

17. Respondents produced no substantial evidence on the subject of the effect of § 14133.3, or of prior authorization, on the non-drug services, (physicians, hospital, etc.), except testimony on the subject of savings on state expenditures. Respondents did produce declarations from several Department pharmacists and M.D.s on the drug service issue. First, their declarations were not as convincing as the in-person expert testimony of petitioner's witnesses. Secondly, the Department declarants founded their opinions upon the untrue premise that non-Formulary drugs could be readily obtained by the Treatment Authorization Request process, (prior authorization), when in fact the evidence was, and the Court finds,—that they cannot be so obtained, (due to the § 14133.3 limitation and due to the TAR-system defects described hereinafter).

18. 22 Cal.Adm.Code § 51303(a) and 51305(a) were formally amended by the Director to reflect the new § 14133.3 standard. Also, the *Manual of Criteria for Medi-Cal Authorization*, (required by 22 Cal.Adm.Code § 51003(e) to be used by Medi-Cal consultants in all prior authorization decisions), was revised September 1982 to provide:

> "... Chapter 328 of the Statutes of 1982 mandated the Department's definition of medical necessity to those services clearly necessary to protect life or prevent serious disability. Effective September 1, 1982, field office consultant will utilize this more stringent definition to approve prior authorization requests.

Provider bulletins,—distributed to all Medi-Cal providers by Computer Sciences Corporation, under the direction and authority of the Director, (RT 332),—all announce that only those

services considered medically necessary to protect life or prevent significant disability will be approved or paid for; and several, considered together, list hundreds of medical procedures which are no longer approved because of the § 14133.3 limitation. (Trial Exhibits 13, 3, 10, 6, 11, 5, and 4).

19. On or about September 1, 1982, the Department of Health Services mailed the Letter alleged in the *First Amended Petition for Mandamus* to all Medi-Cal recipients, announcing the § 14133.3 limitation on coverage and announcing reductions in eyeglasses, eye examinations, hearing aid batteries, drugs, medical supplies, medical transportation, psychiatry, and other services, based on the § 14133.3 limitation.

20. All the Department witnesses were unanimous that § 14133.3, these regulations, Manual of Criteria, and provider bulletins were, are and will be enforced by denying, and not paying for, Required Services and Optional Services which are not, in the opinion of the Department, medically necessary to protect life or prevent significant disability.

21. The Court finds that the Director, Department, and their employees have enforced the § 14133.3 limitation by denying prior authority for, and not paying for, Required and Optional Services, including physicians' services, drugs and procedures, which are medically necessary, but which were not necessary to protect life or prevent significant disability; and thereby, the needy eligible Medi-Cal recipients have been and will continue to be frequently, routinely and prejudicially denied these Medicaid services, which will continue unless respondents are restrained.

22. Based upon the findings in Paragraphs 1 through 5 and Paragraphs 14 through 21, the Court finds and concludes that § 14133.3, the regulations, *Manual of Criteria*, provider bulletins, the Letter, and the acts of Director, Department and employees in enforcing the § 14133.3 statutory/regulatory scheme, are each and all contrary to the Medicaid Act and, therefore, illegal and void, in the same respects and for the same reasons as set forth in paragraphs 6 through 13 herein.

* * * *

PART II

Utilization control.

23. "Utilization controls" contemplated by § 14133, (added 1975, amended 1979), includes:

> "(a) Prior authorization, which is approval by a department consultant, of a specified service in advance of the rendering of that service *based upon a determination of medical necessity* . . .
>
> (b) Postservice prepayment audit, which is *review for medical necessity* and program coverage after service was rendered but before payment is made. *Payment may be withheld or reduced* if the service rendered was not a covered benefit, *deemed medically unnecessary or inapporpriate* . . .
>
> (c) Postservice postpayment audit, which is *review for medical necessity* and program coverage after service was rendered and the claim paid. The department *may take appropriate steps to recover payments* made . . . "

22 Cal. Adm. Code § 51159 also so provides. And, 22 Cal. Adm. Code § 51502(d) provides:

> "The Department may require additional documentation *to determine the medical necessity* of services before paying benefits under the Medi-Cal program.

24. Insofar as justification for services or treatment upon a showing of medical necessity "to protect life or prevent significant disability" is concerned, what has been said in Part I hereof is equally applicable here.

25. The mandate of the Medicaid Act is that physicians, not the State, make the determination of what treatment (and drugs) are proper and "medically necessary" for the needy eligible recipient. 42 U.S.C. § 1396 et seq. This is amply supported. *Beal v. Doe,* 432 U.S. 438, 445, n.9, 448; *Pinneke v. Preisser* (1980) 623 Fed. 2d 546, 550:

> "The decision of whether or not certain treatment or a particular type of surgery is "medically necessary" rests with

> the individual recipient's physician and not with clerical personnel or government officials."

Pinneke also held:

> "The legislative history also supports the conclusion that congress intended medical judgments to play a primary role in the determination of medical necessity. S. Rep. No. 404, 89th Congress, 1st Sess., reprinted in (1965) U.S. Code Cong. & Adm. News, pp 1943, 1986-89." (625 Fed. 2d at 549).

The Medicaid Act was part of the same bill as the Medicare Act, Title XVIII, and a common interpretation is to be given both titles. (*Roe v. Norton* (1975) 522 Fed.2d 928, 940). That Joint Conference Report states:

> (a) *Conditions and limitations on payment for services*
> *(1) Physicians' role*
>
> The committee's bill provides that the physician is to be the key figure in determining utilization of health services—and provides that it is a physician who is to decide upon admission to a hospital, order tests, drugs and treatments, and determine the length of stay. For this reason the bill would require that pyament could be made only if a physician certifies to the medical necessity of the services furnished." U.S. Code Cong. & Adm. News, supra, p 1986.

26. Accordingly, the court concludes that, upon their face, § 14133(a) and 22 Cal.Adm.Code § 51159(a), (prior authorization) are unreasonable and wholly inconsistent with the mandate of the Medicaid Act that treating physicians, not the State, make the determination of what treatment (and drugs) are proper and "medically necessary" for the needy recipient, and hence are contrary to the Medicaid Act and therefore, illegal and void.

Evidence re "medical necessity" denials.

27. The Department of Health Services, (Department), has 12 field offices for processing medical TARS, (RT 345). Only two of these field offices process drug TARS, (RT 348, 120), (except for a small drug TAR office serving the three-county

215); that the withholding of medically necessary drugs at the threshold of minor illnesses inevitably leads in many cases to more serious and more expensive illness, (RT 216); that since the § 14133.3 regulations came in, that the denials are more frequent, (RT 230), that the provider time to obtain telephoned TAR approvals has increased, (RT 230); and, the Department on many occasions denies payment for treatment of Medi-Cal patients during times when the TAR office was closed or the TAR could not be obtained in sufficient time, (RT 233-235). The Court finds that the TAR system, inherently, and as it presently exists, takes control of treatment of the patient away from the physician, (RT 228-231); and that it is professionally impossible for any consultant to obtain enough or proper evidence through the existing TAR system by which to make a professional judgment as to medical necessity. (RT 229).

31. The Court finds that the TAR system inherently, and as it exists, and under § 14133(a), frequently causes Required and Optional Services which are medically necessary to be unavailable to Medi-Cal recipients, and that the procedure is burdensome, onerous, unreasonable and not in the best interests of Medi-Cal recipients.

32. Based on the findings previously made herein, (except Paragraph 26), the Court concludes that § 14133(a) and 22 Cal.Adm.Code § 51159(a), are unreasonable and wholly inconsistent with the mandate of the Medicaid Act that treating physicians, not the State, make the determination of what treatment (and drugs) are proper and "medically necessary" for the needy, and hence are contrary to the Medicaid Act and therefore, illegal and void.

33. The Court is concerned with the obvious fact that when the State is enjoined from reviewing medical necessity *before* the furnishing of a Required Service or an Optional Service, that it can accomplish the very same thing, with the same staff, be reviewing furnished services *afterwards*, when the billing comes in, under §§ 14133(b), (c), and 22 Cal.Adm.Code §§ 51159(b), (c), and 51502(d), and simply render this judgment nugatory in practical effect. The Court concludes that it has inherent jurisdiction, when the same parties are before the Court, and when the

issue of illegality of State determination of "medical necessity" is the same in both cases, and when the illegality of these latter statutes and regulations appears on their face, to rule, and the Court does conclude and rule, that the statutes and regulations mentioned in this Paragraph are unreasonable and wholly inconsistent with the mandate of the Medicaid Act that treating physicians, not the State, make the determination of what treatment (and drugs) are proper and "medically necessary" for the Medi-Cal recipient and are, therefore, illegal and void. (Petitioners having alleged in the First Amended Complaint that the Medi-Cal Act denied funding for services which were medically necessary, and having prayed for peremptory and alternative writ enjoining enforcement of all of 22 Cal. Adm. Code § 51159, and having prayed for restraint from denial of payment on the claim that there was no medical necessity for the service; and having served and filed a proposed Alternative Writ of Mandamus notifying respondents that petitioners were seeking relief against denial of payment for services based on State claims of no medical necessity, therefore, the Court finds that the pleadings have amply raised the issue of a cause of action restraint of enforcement of 22 Cal. Adm. Code 51159 and the same provisions which are set forth in § 141333(b), (c), and 22 Cal. Adm. Code § 51502(d), such that: (a) No amendment of pleadings to conform to proof is required; (b) there is no material variance, and respondents have not been misled to any prejudice. (§§ 469, 470 Code of Civil Procedure).)

34. (Deleted)

PART III

35. Petitioners are each residents of the State of California and taxpayers to the State of California, and all are citizens of the United States and of California except Lorna Purkey; and all have standing to sue to enforce the laws of the state and United States, and to enjoin the illegal expenditure of public funds to enforce §§ 14133.3 and 14133.

36. Lorna Purkey is an AFDC recipient, holder of a valid Medi-Cal card, and as such is a qualified Medicaid and Medi-Cal

recipient. (§§ 14005.1, 11203, and 14018). The Court is advised that she will lose her eligibility in July 1983 due to her dependent child reaching majority. The Court rules that inasmuch as her cause of action for Medi-Cal benefits of restorative breast surgery and follow-up care arose during her eligibility period, that she is entitled to receive the benefits adjudged to her herein, after cessation of AFDC eligibility. In her case, she received left mastectomy May 11, 1982. Her physician found that it was medically necessary for her to have restorative breast surgery, scheduled for August 1982. The TAR was denied August 17, 1982 on the ground that a 6 to 8 month period should elapse. (This decision was illegal, inasmuch as it overruled the judgment of the treating physician re medical necessity of the procedure.) The provider's appeal letter to the Field Office Administrator on September 6, 1982, was denied on the ground that the § 14133.3 limitation precluded coverage. Upon request for fair hearing, Wayne L. Erdbank, M.D., an opthalmologist, State Consultant, wrote a Position Statement January 25, 1983, adding the denial ground that the procedure "is primarily cosmetic" and "attempts to replace a cosmetic defect." First, Mrs. Purkey had no administrative remedy inasmuch as the California Constitution, Article III, § 3.5 precludes an administrative agency from declaring a statute unenforceable; likewise, 22 Cal.Adm.Code § 50951(a). Second, the defenses of unelapsed "6 to 8 months" is not in good faith, inasmuch as more than that period has elapsed. Third, the defense of "cosmetic defect" is not in good faith and is frivolous. The Department has long adopted the definition of cosmetic surgery approved by the C.M.A. which *excludes* " . . . Operations performed to . . . restore parts which were removed in treatment of a tumor . . ." *G.B. v. Lackner*, 80 Cal.App.3d 64, 70. Third, the denial under the limitation of § 14133.3 was illegal, as hereinbefore set out. She is entitled to the restorative surgery sought, and follow-up care at expense of Medi-Cal, regardless of when her Medi-Cal eligibility expires, and without the presentation of any Medi-Cal card.

41. Stephen Cowan is a disabled S.S.I. recipient, holder of a valid Medi-Cal card, and as such is a qualified Medi-Cal recipient. (§§ 14005.1, 12305, and 14018). He has a congenital hole between the lower chambers of his heart, forcing his heart and

respiratory system to work overtime to replace blood leaks, and subjecting him to rapid prejudicial symptoms from otherwise ordinary respiratory ailments. Dr. Lackner, who examined him, testified, and the Court finds, that Sudafed is medically necessary for daytime use as prescribed. Petitioner is entitled to Sudafed upon prescription by his treating physician and all other Required and Optional Services offered by Medi-Cal when determined by his doctor to be medically necessary.

42. In their prayer for relief, petitioners prayed for mandamus ordering payment of medically necessary services when incurred, and for payment of reasonable attorneys fees. Respondents claim as an issue that there has been no appropriation of funds. Countering, petitioners claim as an issue that for violation of federal law, and to enforce federal law, the Supremacy Clause invalidates Article XVI, § 7, California Constitution such that the Superior Court has jurisdiction to order payments against respondents even in the absence of any appropriation, under the doctrine of *Spain v. Mountanos* (1982 9th Cir.) 690 Fed.2d 742. The Court rules that the issue of payment is premature, as the Court expressly reserves the issue of payment, if any, and expressly reserves jurisdiction to subsequently determine the issue of payment or payments. Hence these issues are, presently, premature. (See *Olsen v. Cory*, 140 Cal.App.3d 379, 393.) The Court is presently called upon to determine entitlement, not to presently order payment. See also *Porter v. James* (sic) (1980 Ala.) 499 F. Supp 607, 610:

> "This Court is sympathetic with the struggles of the Governor and the Legislature of Alabama to find the funds to meet the soaring costs of paying the State's share of the expense of Medicaid. But as the Court stated in *Alabama Nursing Home Assn. v. Califiano,* 433 F.Supp. 1325 (1977), . . . :
>
> There is no provision, express or implied, in the Social Security Act permitting a state to alter federal standards to suit its budgetary needs. State participation in Social Security Act programs is voluntary, and the state may withdraw if it wishes. But as long as it remains in a program and accepts federal funds, it must follow the federal statute. . . . If a state could evade the requirements of the Act simply by failing to

appropriate sufficient funds to meet them, it could rewrite the congressionally imposed standards at will. The conditions which Congress has laid down for state participation in Medicaid and other programs would be utterly meaningless. That obviously is not the case. Consequently, Alabama must meet the statutory requirements so long as it remains in the Medicaid Program, regardless of budgetary considerations."

43. Petitioners had and have no effective administrative remedy.

44. Petitioners Purkey, Cowan and Dupont have standing to assert here an unlawful threat to their present and future welfare to which they are entitled under the Medicaid Act.

45. Petitioners had and have no plain, adequate or speedy relief, and have suffered and will suffer great, immediate and irreparable injury.

46. Respondents claim as defense that the Health Care Financing Administration, (HCFA), of the federal Department of Health and Human Services, has by letter dated March 29, 1983, approved the State Plan in most respects. First, the record was left open for the respondents to file such decision, and the Court hereby admits into evidence that letter of approval, and the documents and declarations attached to respondents' *Points and Authorities in Support of Motion to Reconsider*, and has considered that evidence. Second, it does not appear from these exhibits that the State Plan presented to HCFA is substantially the same as the statutes, § 14000 et seq, especially, § 14133.3. In particular, § 14133.3 is not mentioned anywhere, apparently, in the documents furnished HCFA. Program coverages are *affirmatively represented* therein, to HCFA, as covering "medically necessary" situations, when such is emphatically not the case. For expample, Item 5 of the *Medi-Cal Benefits Chart*, namely, physicians' services, states: "PROGRAM COVERAGE** . . . as medically necessary, subject to limitations; however, experimental services are not covered." The footnote states merely:

"**Coverage is limited to medically necessary services as defined in Section 51303(a)."

One would have to be especially astute to apprehend from such presentation of the "State Plan" that physicians' services are drastically curtailed to only those "medically necessary to protect life or prevent significant disability." Indeed, a "State Plan" approval application to HFCA, containing no more information than is disclosed by the documents here admitted into evidence, is not a fair representation of the facts to the federal agency, to say the least. Third,—and most importantly,—the HCFA decision is relevant, but not controlling. Based upon the evidence, and the actual statutory/regulatory scheme and its enforcement by respondents which was presented in this Court, the decision by this Court remains the same.

47. The Court notes that BEVERLEE A. MEYERS is no longer Director of the Department of Health Services, and that PETER RANK is presently her successor, as Director of the Department; and as such, he is ordered, and is hereby, joined as a respondent, in his said official capacity.

48. Petitioners are entitled to move for reasonable attorneys fees, and for their motion to be determined, under § 1021.5 C.C.P. and under the private attorney general principle; and the Court expressly reserves jurisdiction to receive, hear, and determine said motion for attorneys fees, and to order attorneys fees to be paid.

49. There is no misjoinder of parties.

50. Petitioners are entitled to a judgment and peremptory writ of mandamus and other orders in conformity with this Statement of Decision.

Dated: May 31, 1983.

WM. A. WHITE
Judge

PETITION FOR REVIEW

To the Honorable Supreme Court of the State of California:

Stephen Cowan, Chester Dupont, Lorna Purkey and Frederick S. Mayer, ("Petitioners"), petition for review of the entire decision, in whole and in every part, of the COURT OF APPEAL OF THE STATE OF CALIFORNIA, THIRD APPELLATE DISTRICT, filed December 9, 1986. (Copy annexed as Exhibit A).

Petitioners duly filed a Petition for Rehearing in the Court of Appeal, which was denied January 7, 1987. (Copy of order denying rehearing is annexed as Exhibit B.)

Rule 28 Statement

(1) Review by the Supreme Court is necessary to settle important questions of law, namely:

Does the limitation of Medi-Cal coverage in Secs. 14133.3, (as amended 1985) and 14059.5 Welfare & Institutions Code,[1] to only those services:

> " . . . reasonable and necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain,"

violate the federal Medicaid Act, (Title XIX of the Social Security Act of 1956), *upon its face*, in that:

(i) these limitations are unreasonable and inconsistent with the objectives of the Medicaid Act, (Rule of *Beal v. Doe*, 432 U.S. 438, 444, 53 L.Ed.2d 464, 97 S.Ct. 2366, 2371);

(ii) the standard of treatment, as so limited, is unsufficient in amount, duration and scope to reasonably achieve its purpose, (in violation of 42 C.F.R. 440.230(b), which provides:

> "Each service must be sufficient in amount, duration and scope to reasonably achieve its purpose."), and,

---

[1]All references are to the Welfare & Institutions Code, unless otherwise indicated.

(iii) these California Medi-Cal statutes arbitrarily deny and reduce the amount, duration and scope of Required Services solely because of the diagnosis, type of illness, and condition of recipients, in violation of 42 C.F.R. 440.230(c) which provides in pertinent part:

> "The Medicaid agency may not arbitrarily deny or reduce the amount, duration or scope of a required service . . . solely because of the diagnosis, type of illness or condition."

(2) Review by the Supreme Court is necessary to settle an important question of law, namely:

Does State approval, i.e., "second-guessing," of medical necessity for prior authorization and for post-service payment,—as required by Secs. 14133(a),(b),(c), and 14133.3 (amended 1985),—violate the Medicaid Act requirement that the treating physician, not the State, make the determination of what treatment and drugs is medically necessary?

(3) Review by the Supreme Court is necessary to settle an important question of law, namely:

Does the prior authorization system, *as implemented in fact by Medi-Cal*, substantially interfere with the determination by the physician of the medical necessity for the treatment or drugs prescribed, in violation of the Medicaid Act?

(4) Review by the Supreme Court is necessary to settle an important question of law, namely:

Does the prior authorization system, as *implemented by Medi-Cal*, frequently cause *covered services* to be unavailable so as to be burdensome, onerous, unreasonable and not in the best interests of Medi-Cal recipients, in violation of 42 C.F.R. 440.230(b), which provides that each service must:

> '. . . be sufficient in amount, duration and scope to reasonably achieve its purpose.",

and in violation of 42 U.S.C. Sec. 1396a(a)(19), which provides that a State plan must:

> " . . . provide such safeguards as may be necessary to assure that . . . such care and services will be provided in a manner

> consistent with simplicity of administration and the best interests of the recipients.",

and, in violation of 42 U.S.C. Sec. 1396a(a)(22) which requires:

> " . . . standards and methods that . . . assure that medical or remedial care and services provided to recipients of medical assistance are of high quality."

(5) Review by the Supreme Court is necessary to secure uniformity of decision, in that the Court of Appeal of the State of California, Second Appellate District, has ruled, in *Janeski v. Myers* (1984) 163 Cal.App.3d 18, (petition for hearing denied by California Supreme Court, cert. den. by U.S. Supreme Court), that:

(i) federal regulations, (i.e., 42 C.F.R. 440.230(c)), do not permit discrimination on the basis of the "medical disorder for which a person suffers,"

(ii) the Medi-Cal drug prior authorization system, as implemented by Medi-Cal, violates the Medicaid Act in that a pharmacist, not a licensed medical doctor, "second guesses" the treating physician by approving or disapproving drugs prescribed by the treating physician and submitted as a treatment authorization request, (called a "TAR"), and,

(iii) the Medi-Cal drug formulary and prior authorization system, by attempting:

> " . . . to delete and require prior approval for drugs that often provide only minor relief of less serious conditions,"

violates the Medicaid Act requirement that, where an Optional Service is offered by a state Medicaid agency, it must be furnished when medically necessary.[2]

---

[2] *Janeski v. Myers* holds in part:

> "(B)y making certain drugs totally unavailable, ((Medi-Cal)) ignored the necessity that some patients have for drugs that might be merely palliative for others. Infants and elderly people, for example, often suffer greatly from conditions that might be very minor in the rest of the population. Such decisions must most often

On the other hand, the *Cowan v. Meyers* decision of the 3rd D.A.A. in case at bar is directly contrary to the 2d D.C.A. decision in *Janeski v. Myers* in respect to the three issues listed immediately above, which conflict, under any view, must be resolved by the California Supreme Court.

The stakes in this lawsuit and in this Petition for Hearing are enormous. As eloquently stated by the dissenting opinion in case at bar:

> "The consequences . . . will be visited upon the tens, perhaps hundreds, of thousands of persons who will be denied needed medical services because their illnesses are less than life threatening or are deemed less than significant or are accompanied by pain that is less than severe." (Page 1 of slip dissenting opinion.)

From the State's viewpoint:

> "This case involves serious issues affecting recipients, providers, and the state, ((and)) the potential costs are well over $1 billion. . . .". (Telegram of Attorney General to California Supreme Court in a prior, preliminary proceeding in case at bar.)

* * *

(Remainder of Petition for Review deleted.)

(END OF APPENDIX)

---

be made on a patient-by-patient basis. Respondents have attempted to delete or require prior approval for drugs that often provide only minor relief or less serious conditions; their general rational basis, however, does not help the Medi-Cal recipient who, because of 'medical necessity, requires the deleted medication."

No. 87-17

In The

Supreme Court of the United States

October Term, 1986

Supreme Court, U.S.
FILED
JUL 29 1987
JOSEPH F. SPANIOL, JR.
CLERK

STEPHEN COWAN, CHESTER DUPONT, LORNA PURKEY and FREDERICK S. MAYER,

Petitioners,

vs.

BEVERLEE A. MEYERS, Acting Director, Department of Health Services, State of California; KENNETH KIZER, Director, Department of Health Services, State of California; DEPARTMENT OF HEALTH SERVICES, State of California; GRAY DAVIS, Controller, State of California; and JESSE UNRUH, Treasurer, State of California,

Respondents.

On Writ of Certiorari to the Court of Appeal, State of California, Third Appellate District

BRIEF FOR RESPONDENTS IN OPPOSITION

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BRIEF FOR RESPONDENTS IN OPPOSITION

STATEMENT OF THE CASE

On May 31, 1983, the Superior Court in and for the County of Sacramento issued an order which in effect promulgated a new and dramatically different Medi-Cal[1] program for the State of California.

First, the Superior Court redefined and broadened the definition of the term "medical necessity." This term is

1. Medi-Cal is California's name for its Medicaid program.

crucial to the provision of Medi-Cal benefits because only medically necessary benefits are provided and funded.

The trial court, in essence, held that the new definition of "medical necessity" found in California Welfare and Institutions Code section 14133.3 illegally interfered with the relationship between the recipient-patient and the physician in that it allowed the Department of Health Services to define medical necessity and did not defer solely to the physician's determination.

The trial court also held that the section 14133.3 definition was illegal because it was inconsistent with the objectives of the federal Medicaid Act in that the services provided were insufficient in amount, duration and scope to reasonably achieve their purposes.

The trial court so held in spite of the fact that the federal government had approved California's new definition of medical necessity.

The superior court's second major revision of the Medi-Cal program was the elimination of all prior authorization. Prior authorization (implemented through documents called "treatment authorization requests" or "TARS") is that scheme which requires certain benefits to be approved by Medi-Cal *before* they are provided to the recipient. This prior authorization system has long existed in California and has been long approved by the federal government. This system works both as a utilization control (i.e., a guard against abuse) and a guarantee (i.e., if a provider obtains a TAR, he is assured of reimbursement by Medi-Cal). Proper utilization controls are

required by the federal government before it will participate, by way of funding, in a state Medicaid plan.

The TAR system attempts to insure that only medically necessary services are provided and funded. All services are not subject to TARS. Only certain services require a TAR approval. TARS are submitted by the provider to DHS whose medical professionals review them for approval. DHS medical professionals work through personnel trained to evaluate TARS. The staff can review TARS submitted on written form or by telephone. An appropriate medical professional is available to discuss TARS with providers, i.e., DHS pharmacists are available to consult with provider pharmacists, etc. The time for TAR approval is routinely a matter of a few days and immediate telephone approval is possible. During the nonworking hours, services can be provided without TARS and will be funded if appropriate. Similarly, in emergencies, services can be provided without TARS and will be funded if an emergency existed. Every effort, within the confines of fiscal limitations, is made to insure prompt, efficient, intelligent responses to TARS.

The trial court held that the TAR system (which was required and approved by the federal government) illegally interfered with the relationship between the recipient-provider and physician. The trial court also held that the TAR system was fatally inconsistent with the federal Medicaid Act.

In its opinion, the District Court of Appeal for the Third District corrected both errors committed by the trial court, to wit: The definition of "medical necessity" was held to have been correctly promulgated by the state as a

"macro-decision" and the prior authorization system utilized by California was held to be legal and proper. This opinion was not disturbed by the Supreme Court of California, nor should this Court grant the Petition for Writ of Certiorari.

SUMMARY OF ARGUMENT

The petition seeks to disturb a correct statement of the law by the California District Court of Appeal regarding the definition of "medical necessity" and utilization controls within the Medi-Cal System. The California District Court of Appeal correctly set forth applicable federal and state law in holding that neither California's definition of "medical necessity" nor its utilization control system violates the Social Security Act of 1965.

ARGUMENT

I

THE CALIFORNIA STATE COURTS CORRECTLY DETERMINED THAT CALIFORNIA'S DEFINITION OF MEDICAL NECESSITY IS CONSISTENT WITH FEDERAL LAW

The appellate court correctly held that California's definition of medical necessity was consistent with federal law.

For this Court's convenience, Welfare and Institutions Code section 14133 (as it then read) will be set forth in full here:

> "(a) The director shall require fully documented medical justification from providers that the requested services are medically necessary or protect life or prevent significant disability, on all requests for prior authorization.
>
> "(b) For services not subject to prior authorization, the director shall additionally determine utilization controls which shall be applied to assure that the health care services provided and the conditions treated, are medically necessary to protect life or prevent significant disability. Such utilization controls shall take into account those diseases, illnesses, or injuries which require preventive health services, or treatment to prevent serious deterioration of health.
>
> "(c) Nothing in this section shall preclude payment for family planning services, early or periodic screening, diagnosis and treatment services mandated by federal law."

The trial court had incorrectly held that California's definition was twice flawed: (1) the definition was an interference with the relationship between the recipient-patient and physician (or other medical professional); and (2) the definition was inconsistent with the objectives of the Medicaid Act, Title XIX of the Social Security Act of 1965, at 42 U.S.C. 1396a et seq. The trial court's holdings on both points were erroneous. The trial court's incorrect rulings were based upon an erroneous reading of *Pinneke v. Preisser* (8th Cir. 1980) 623 F.2d 546; *Preterm, Inc. v. Dukakis* (1st Cir. 1979) 591 F.2d 121, and other related cases.

A. The Appellate Opinion Correctly Held That The Physician Is Not The Sole Arbiter Of Medical Necessity

In *Preterm,* the appellants had sought an injunction to prohibit enforcement of a Massachusetts statute which permitted public funding of abortions only to prevent the death of the mother and in cases where an abortion was necessary for the proper treatment of victims of forced rape or incest. The United States Court of Appeals for the First Circuit held, inter alia, that a state may not discriminate against a specific medical condition (abortion) by utilizing a more stringent definition of medical necessity for its treatment than for other medical conditions. Massachusetts could not utilize one definition of medical necessity for all medical conditions except abortions and utilize a different, more exclusionary, definition of medical necessity as a threshold to funding abortions. (*Preterm, Inc. v. Dukakis, supra,* 591 F.2d at 126.) California, on the other hand, uses a single standard.

Moreover, *Preterm* teaches that the decision as to what is a medical necessity is a two-step analysis. Generally, the state Legislature promulgates a statute which determines which types of medical assistance are included within its plan and which types are not (a "macro-decision"). Specifically, the physician determines whether a type of included assistance is medically necessary to his patient (a "micro-decision"). (*Id.* at 125.)

In the instant case, the trial court incorrectly relied on *Preterm* to support its ruling that a patient's physician is the sole arbiter of medical necessity, thus leading to the conclusion that the state and its taxpayers must pay for

any medical assistance a physician determined as medically necessary. This would inevitably lead to a high level of medical coverage that, it is safe to speculate, most taxpayers would deny even themselves.

The appellate court correctly read *Preterm* and concluded that, as a matter of law, the physician is not the sole arbiter of medical necessity. The physician decides only which of the legislatively predetermined coverages are medically necessary to the patient, not the total scope of coverage.

The trial court's reliance on *Pinneke v. Preisser, supra,* 623 F.2d 546 was also misplaced. Citing *Pinneke,* the trial court opined that the physician was the sole arbiter of medical necessity. This plainly erroneous reading of the decision was rectified by the Appellate Court.

In *Pinneke,* the recipient-patient sought sex reassignment surgery, which was refused as not medically necessary. Pinneke was diagnosed as a female personality within a male body. Sex reassignment surgery was established as the only treatment for this condition. The surgery was determined to be medically necessary by her physician. (*Pinneke v. Preisser, supra,* at 547-548.) The appellate court ordered, inter alia, public funding for the surgery.

The Iowa Department of Social Services had established, without formal rule-making proceedings or hearings, an *irrebuttable* presumption that the sex reassignment surgery could *never* be medically necessary. The appellate court stated that the irrebuttable presumption (promulgated informally) reflected an "inadequate solicitude for [Pinneke's] diagnosed condition, the treatment prescribed

by [Pinneke's] physicians, and the accumulated knowledge of the medical community." (*Pinneke v. Preisser, supra,* at 549.)

The court went on to hold:

> ". . . Congress intended medical judgments to play a primary role in the determination of medical necessity. [Citations omitted.]
>
> "The decision of whether or not certain treatment or a particular type of surgery is 'medically necessary' rests with the individual's physician and not with clerical personnel or government officials. And as stated in *White v. Beal* (3rd Cir. 1977) 555 F.2d 1146 'The regulations permit discrimination in benefits based upon the degree of medical necessity but not upon the medical disorders from which the person suffers.' " (*Pinneke v. Preisser, supra,* 623 F.2d at 550.)

Clearly, in the instant case, the trial court misapplied the holding in *Pinneke.* The *Pinneke* court, much like the *Preterm* court, held that a specific medical condition cannot be discriminated against by the use of a definition of medical necessity which effectively precludes any treatment for that condition. The *Pinneke* court also held that it is permissible for a state to promulgate regulations which limit benefits, across the board, based upon a more stringent definition of medical necessity.

In sum, the trial court misinterpreted pertinent case law. The Court of Appeal properly corrected this misinterpretation. The Court correctly held that the physician is not the sole arbiter of medical necessity and that the Medicaid statutes and regulations permit a state to define medical necessity in a way tailored to the requirements of its own Medicaid program.

In reaching this conclusion, the Court of Appeal correctly read *Rush v. Parham* (5th Cir. 1980) 625 F.2d 1150. In *Rush,* plaintiff brought suit to compel the state to pay for her transsexual surgery, which the state had refused to do. Rush claimed the refusal violated the federal Medicaid Act. Rush's physician had determined that the transsexual surgery was medically necessary. The state had refused funding on two bases: (1) the surgery was "experimental," and (2) the surgery, in the opinion of the state, was inappropriate treatment for Rush. Rush moved for summary judgment on two grounds: (1) the state could not, as a matter of law, deny funding for a service which two private physicians had deemed, in their judgment, to be medically necessary, and (2) the state, as a matter of law, had abused its discretion by determining that transsexual surgery was inappropriate treatment for Rush. The trial court granted Rush's motion, holding that the state must pay for all medically necessary services of Medicaid recipients and that the determination of Rush's physician that transsexual surgery was medically necessary could suffer no interference from the state. The Circuit Court of Appeals reversed and remanded.

Pertinent here, the *Rush* court specifically held that, ". . . a state Medicaid agency can review the medical necessity of treatment prescribed by a doctor on a case-by-case basis." The court's language is illuminating:

> "The district court has, in effect, held that a state has no role in determining whether a particular service is medically necessary. In our view, however, the Medicaid statutes and regulations permit a state to define medical necessity in a way tailored to the requirements of its own Medicaid program. Our analysis begins with the statute, which provides that:

> "A State plan for medical assistance must . . . include reasonable standards . . . for determining eligibility for and the extent of medical assistance under the plan which . . . are consistent with the objectives of this [title].

"42 U.S.C. § 1396a(a)(17) (1976). The Supreme Court has interpreted this language as conferring broad discretion on the States to adopt standards for determining the extent of medical assistance, requiring only that such standards be 'reasonable' and 'consistent with the objectives' of the Act. *Beal v. Doe,* 432 U.S. 438, 444, 97 S.Ct. 2366, 2371, 53 L.Ed.2d 464 (1977). Under the district court's decision, however, the states would only have discretion to exclude from coverage the so-called optional services listed in sections 1396(a)(6)-(17). The general language of section 1396a(a) suggests that Congress intended the states' discretion to be considerably less circumscribed.

"The key to defining the states' role in determining the extent of coverage can be found in the Supreme Court's use of the word 'standard' in the passage we quoted from *Beal v. Doe.* We think the Court was saying that a state may establish standards for individual physicians to use in determining what services are appropriate in a particular case. This state responsibility to establish standards extends at least to the shaping of a reasonable definition of medical necessity. The Department of Health and Welfare regulations so provide: 'The [state] agency may place appropriate limits on a service based on such criteria as medical necessity. . . .' (42 C.F.R. § 440.230(d).)

"This does not remove from the private physician the primary responsibility of determining what treatment should be made available to his patients. We hold only that the physician is required to operate within such reasonable limitations as the state may impose. This same relationship between the private physician and government exists in the federal Medi-

> care program, which, like Medicaid, is centered around the judgment of the private physician. See 42 U.S.C. § 1396a(a)(23) (1976) (Medicaid recipients permitted freedom of choice in selecting a physician) and 42 U.S.C. § 1395a (1976) (similar Medicare provisions)." (*Rush v. Parham, supra,* 625 F.2d at 1155-1156.)

Rush teaches that treatment funded by Medicaid is a cooperative, bilateral exercise between the physician and the state (including its taxpayers) who pay the bills. The Appellate Court correctly ruled that Medicaid treatment was not a unilateral endeavor by the physician.

B. Federal Medicaid Regulations Permit California To Define Medical Necessity.

The Appellate Court held that California's definition of medical necessity was consistent with the objectives of the federal Medicaid Act. This holding should not be disturbed, it is correct as a matter of law. 42 C.F.R. section 440.230 permitted California to define the term "medical necessity." 42 C.F.R. section 440.230 provided in pertinent part:

> "(c) The Medicaid agency may not arbitrarily deny or reduce the amount, duration, or scope of a required service under §§ 440.210 and 440.220 to an otherwise eligible recipient solely because of the diagnosis, type of illness, or condition.
>
> "(d) The agency may place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures."

The trial court relied specifically on subsections (a)(2)(b) and (a)(2)(c) to contend that the state plan, as embodied in section 14133.3, is fatally inconsistent with federal Social

Security Law. The trial court was wrong. Subsection (a)(2)(d) authorized states to " . . . place appropriate limits on a service based on such criteria as medical necessity. . . . "

By adopting section 14133.3, California placed a limit on services by redefining medical necessity. Section 14133.3 defined medical necessity as a medical service required " . . . to protect life or prevent significant disability . . . " The showing of a medical necessity triggered the provision of services. California previously provided medical services, "as medically necessary." (22 Cal. Admin. Code, § 5100(E).)

The New Jersey Supreme Court ruled that such limitations are lawful and consistent with the Social Security Act. (*Dougherty v. Human Services Dept.* (91 N.J. 1, 1982) 449 A.2d 1235.) In *Dougherty,* medical assistance, in the form of the purchase price ($269) of an air cleaner, was denied to the mother of an asthmatic child. This denial was based on a state regulation, which denied payment for items which were environmental control equipment, whose primary and customary use was nonmedical. After exhausting all levels of her administrative remedy, the mother resorted to the courts and eventually arrived in the New Jersey Supreme Court. Dougherty argued, in part, that the state regulation was inconsistent with the federal Social Security Act. The court's reasoning rejecting this argument is compelling:

> "Although Title XIX does not require states to provide funding for all medical treatment falling within the five general categories, it does require that 'State medical plans establish "reasonable standards . . . for determining . . . the extent of medical

assistance under the plan which . . . are consistent with objectives of [Title XIX]," 42 U.S.C., § 1396a(a)(17) . . . . *Beal v. Doe,* 432 U.S. 438, 441, 97 S.Ct. 2366, 2369, 53 *L.Ed.*2d 464, 470 (1977). We have never held that our statutory program requires state reimbursement for all medically necessary services for every patient. *Monmouth Medical Center v. State,* 80 N.J. at 309, 403 A.2d 487 (footnote omitted) (1979)."

"There are two questions, then, in this case. Is the agency regulation valid, and was it correctly applied as to this claimant, i.e., was the order of waiver proper?

"In *Texter v. Dept. of Human Services,* 88 N.J. 376, 443 A.2d 178 (1982), we recently restated the principles governing review of agency regulations. We held there that '[a]dministrative agencies have wide discretion in selecting the means to fulfill the duties that the Legislature delegated to them.' *Id.* at 383, 443 A.2d 178. N.J.S.A. 30:4D-5 and 4D-7 authorize the agency and the Commissioner to adopt rules and regulations to implement the policies of the act. On review, courts presume that an administrative regulation is valid. The burden is on the challenger to demonstrate that the regulation is arbitrary, capricious or unreasonable. *Aid D. v. Long* (1978) 75 N.J. 544, *New Jersey Guild of Hearing* 384 A.2d 795 (1978); *Cole Natl Corp. v. State Bd. of Exam. of Ophal. Disp.,* 57 N.J. 227, 231, 271 A.2d 421 (1970). A court will not substitute its judgment for the expertise of the agency. *New Jersey Guild, supra,* 75 N.J. at 562, 384 A.2d 795.

"In fulfilling its statutory mandate, the Division has adopted a comprehensive manual for the administration of the program. N.J.A.C. 10:49-1.1 *et seq.* Its several hundred pages give detailed descriptions of eligible items such as orthotic appliances, N.J.A.C. 10:55-1.1 *et seq.,* coverage for physical therapy, N.J.A.C. 10:53-1.6, and payment allowed for prescription

drugs. N.J.A.C. 10:51-6.18. In the subchapter entitled 'Medical Supplier Manual,' the agency specified certain noncovered items including personal incidentals, gauze, bandages, and orthopedic mattresses. N.J. A.C. 10:59-1.6. In subsection (a)(6) the following items were excluded from coverage:

> "Environmental control equipment and supplies (for example, air conditioners, humidifiers, dehumidifiers, electrostatic filters and so forth: 1. exceptions are vaporizers and cool mist humidifiers.)

"The record does not disclose the reason for each exclusion. The agency argues that environmental equipment was excluded from coverage because it not only serves the medical needs of the patient but also aids the comfort and convenience of all of the members of the household. No one would deny that surgical gauze is necessary for medical treatment of a wound or that other appliances may be necessary for medical treatment, but an agency administering so vast and complex a program can well determine that such choices must be made and that certain items deserve different treatment. Judicial supervision of such classifications would be unwise. Establishment of priorities is best left to the legislative branch and executive agencies. Since the standards adopted were reasonable and consistent with the objectives of the Medicaid Act, the Appellate Division found that regulation to be valid. We agree." (*Dougherty v. Human Services Dept.* (91 N.J. 1, 449 A.2d at 1238 (1982).)

The *Dougherty* Court specifically noted (in a footnote) that New Jersey did not violate section 440.220 in that it did not deny or exclude services on the basis of a specific condition. *Dougherty v. Human Services Dept., supra,* 449 A.2d 1238, fn. 2. The court then went on to rule in Dougherty's favor on grounds unrelated to those at bar.

It is important to emphasize that the facts of *Dougherty* and the instant case were very similar. There was no exclusion from treatment of a specific medical condition. A comprehensive manual for administration of the program has been promulgated. The manual described objective criteria by which to measure a physical condition to ascertain if it is a medical necessity. Both state programs (New Jersey's and California's) were (and still are) vast and complex. No one in either case was denied vital services. In sum, the limitation in *Dougherty* and the limitation (pursuant to the current definition of medical necessity) in the case at bar were (not and are not) arbitrary or capricious.

California was empowered by 42 C.F.R. section 440.230(a)(2)(d) to place limitations on services based upon medical necessity. California had done exactly that. The promulgation of the current medical necessity definition had not rendered any medical service insufficient in amount, duration and/or scope so that it was unable to achieve its purpose.

In conclusion, California had done precisely what 42 C.F.R. section 440.230(a)(2)(d) permitted. Such action was consistent and compatible with the objectives of the Social Security Act.

The *Dougherty* court's analysis has been reflected or supported by federal cases. (*Curtis v. Taylor* (5th Cir. 1980) 625 F.2d 645; *Virginia Hospital v. Kenley* (1977) 427 F.Supp. 781.) This is the only analysis of 42 C.F.R. section 440.230 which gives meaning and harmonizes all of its language. This is precisely the sort of construction which the trial court erroneously did not utilize. (See

United States v. Menasche (1955) 348 U.S. 528; see also *Pinneke v. Preisser, supra,* 623 F.2d 546; *Rush v. Parham, supra,* 591 F.2d 121.)

In sum, the District Court of Appeals correctly interpreted the applicable case law. Its correct ruling should not be disturbed and the petition should be denied.

II

CALIFORNIA'S TAR SYSTEM IS LEGAL AND CONSISTENT WITH FEDERAL LAW

The trial court struck down California's entire prior authorization scheme. This scheme is implemented through the use of forms called Treatment Authorization Requests —TARS. It essentially held that the TAR system is an improper utilization control and so interferes with the relationship between the patient-recipient and the medical professional-provider that it is fatally inconsistent with the objectives of the federal Social Security Act. The Appellate Court corrected this fallacious conclusion and upheld California's prior authorization scheme.

This Court should also be mindful that, as previously demonstrated, the individual physician is not the sole arbiter of medical necessity.

This Court should lastly be mindful that the TAR process does not hinder emergency care; i.e., in emergencies, the provider does not need to satisfy the TAR procedure.

The federal government permitted states to "... place appropriate limits on a service based on ... utilization control procedures." (42 C.F.R. § 440.230(a)(2)(d).) The

long existing TAR system (Dr. Lackner testified that he used the TAR system when he was Director of the Department of Health; RT 245) is precisely that—a utilization control procedure.

Welfare and Institutions Code section 14133 provided:

> "Utilization controls that may be applied to the services set forth in Section 14132 which are subject to utilization controls shall be limited to:
>
> "(a) Prior authorization, which is approval by a department consultant, of a specified service in advance of the rendering of that service based upon a determination of medical necessity. Prior authorization includes authorization for multiple services which are requested and granted on the basis of an extended treatment plan where there is a need for continuity in the treatment of a chronic or extended condition.
>
> "(b) Postservice prepayment audit, which is review for medical necessity and program coverage after service was rendered but before payment is made. . . .
>
> "(c) Postservice postpayment audit, which is review for medical necessity and program coverage after service was rendered and the claim paid. . . .
>
> "(d) Limitation on number of services, which means certain services may be restricted as a number within a specified time frame.
>
> "(e) Review of services pursuant to Professional Standards Review Organization agreements entered into in accordance with Section 14104."

California courts have not found any illegality in pertinent areas of California's prior authorization scheme. (*California Chiropractic Ass'n v. Human Relations Agency* (1979) 91 Cal.App.3d 141; see generally *Margulis v. Meyers* (1981) 122 Cal.App.3d 338.) This is especially noteworthy since Congress intended that states be given con-

siderable discretion and latitude in implementing their Medicaid plans. *(Dist. of Col. Pod. Suc. v. District of Columbia* (D.C. 1975) 407 F.Supp. 1259, 1263.)

Margulis is particularly instructive. The Court upheld a prior authorization scheme in the form of TARS which was imposed on the provider as a utilization control. This TAR scheme was required for all services rendered on behalf of all Medi-Cal patient-recipients. This approved TAR scheme was more stringent than the TAR scheme in use for the services disputed in the case at bar.

Respondent's evidence clearly established that the TAR system has been well established for numerous years, that it had previously been reviewed and approved by the federal government, that it had been continuously refined and tuned to provide expeditious, efficient and equitable service to the medical professional-provider and the patient-recipient, and that the federal government had indeed approved the current medical necessity definition and TAR scheme.

It must be emphasized that not all services require a TAR. (See *Margulis v. Meyers, supra,* 122 Cal.App.3d at 339.)

It is beyond peradventure that,

> ". . . [w]here, as in the Medi-Cal program, limited funds are available, the imposition of more onerous restrictions upon provider services for those conditions which may generally be viewed as less life-threatening than those imposed with respect to the services of providers who do frequently deal with life-threatening situations, is clearly supported by a rational basis." (*California Chiropractic Ass'n v. Human Relations Agency, supra,* 91 Cal.App.3d at 150.)

Respondent's evidence clearly established the many efforts made to reduce any inconvenience. California's utilization controls were inarguably necessary, plainly efficient and patently legal. The Appellate Court correctly recognized this fact in its opinion. That opinion should not be disturbed. The Petition for Writ of Certiorari should be denied.

CONCLUSION

For the foregoing reasons this Court should deny the Petition for Writ of Certiorari. The California appellate opinion is a correct statement of the law. No further review should occur.

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